# BASICS OF IPR AND PATENTS

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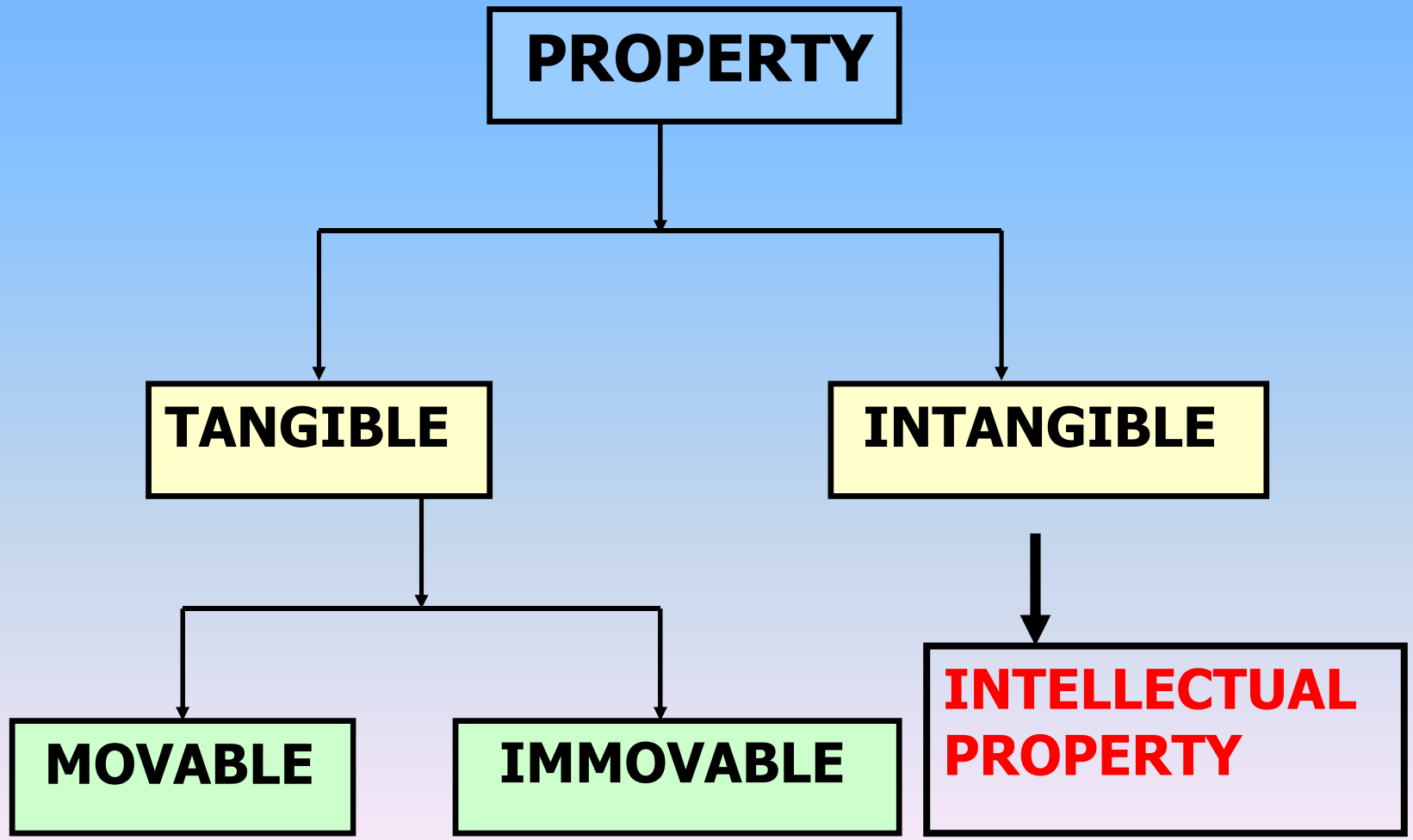
# INTELLECTUAL PROPERTY RIGHTS

# *"The product of thought, creativity and intellectual effort"*



# INTELLECTUAL PROPERTY RIGHTS

- Intellectual property results from the creations of intellect in industry, scientific, literary and artistic domain and is intangible.

- Intellectual Property Rights (IPR), very broadly, are the exclusive rights granted to creators and owners of works that are results of human intellectual creativity or owner of the said property for its commercial exploitation subject to the provisions of national laws and international agreements.

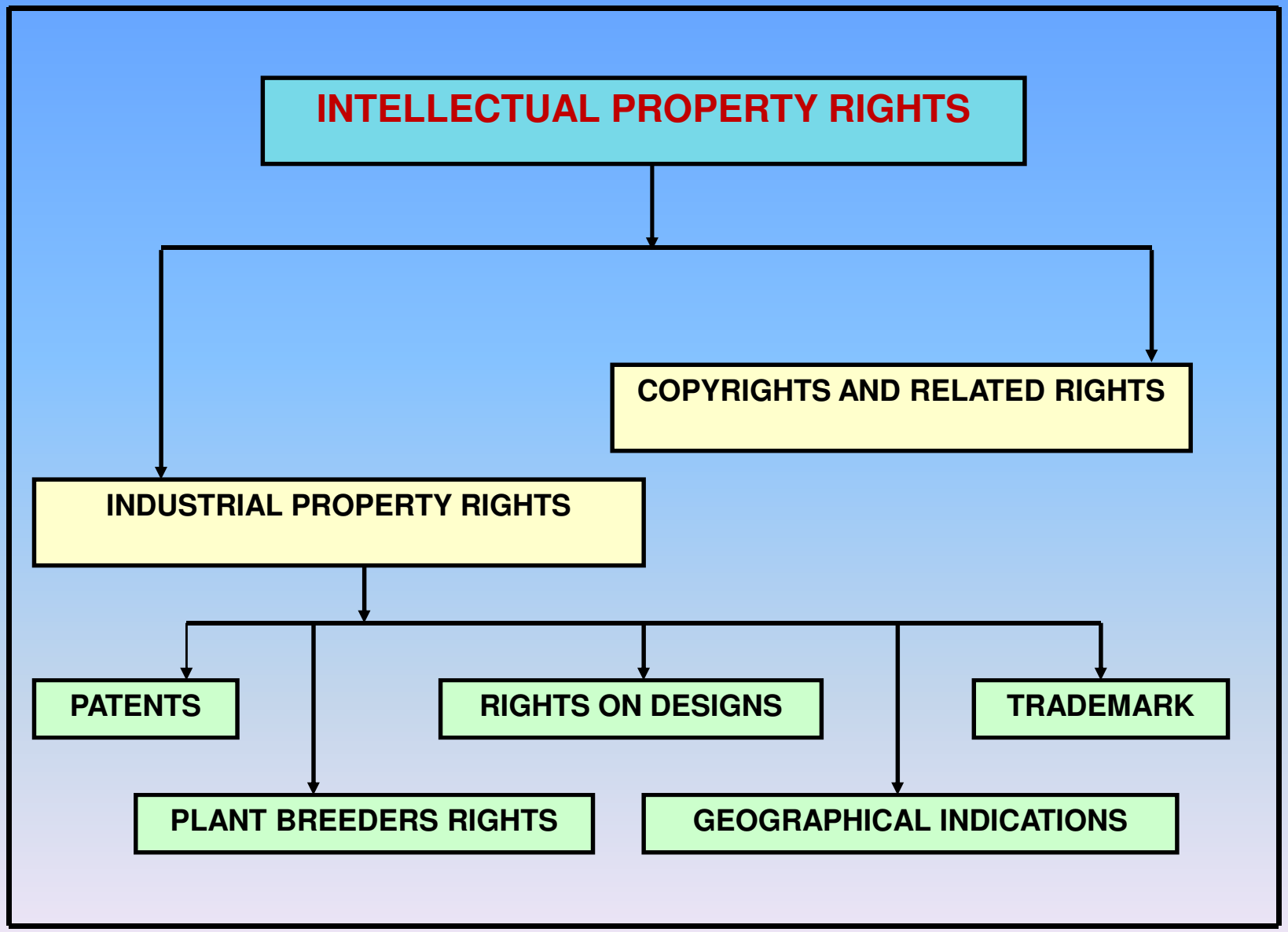
- IPR can be in the form of an invention, a manuscript, a suite of software, or a business name.

# THE PURPOSE OF SUCH GRANT

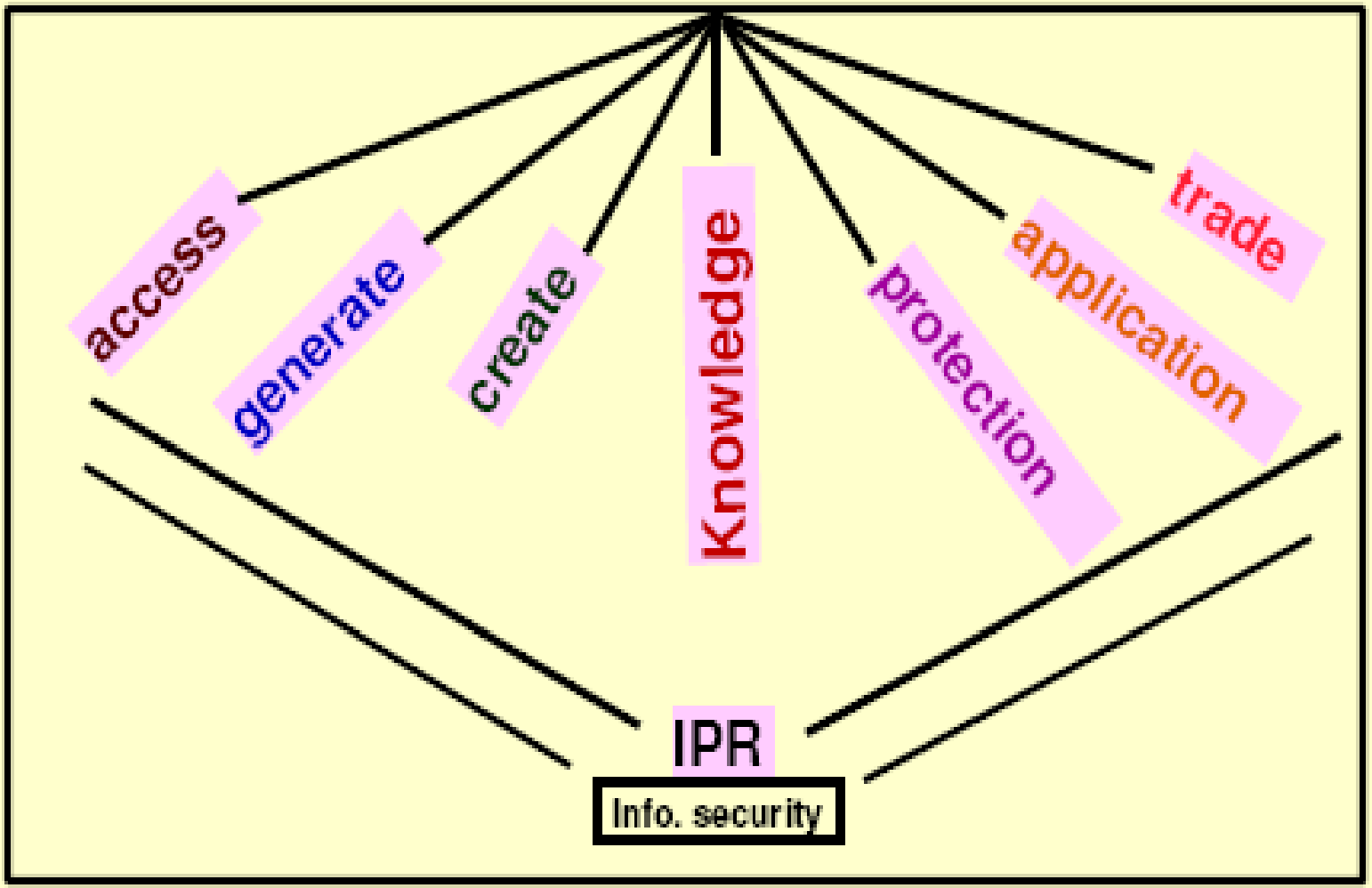
- To provide incentive towards various creative endeavors of the mind by offering protections.
- To give such creators official recognition.
- To create repositories of vital information.
- To facilitate the growth of both domestic industry or culture and international trade through the treaties offering multilateral protection.

- **Intellectual property rights can be broadly divided into two**
  - **Industrial property rights**
  - **Copyrights and Related rights**

- **Industrial property rights include patents, rights on industrial designs, rights on Trademarks and Geographical Indications, rights on new variety of plants etc, Law of confidential information and passing off. Protection also extends to scientific discoveries know-how/expertise and trade secrets.**

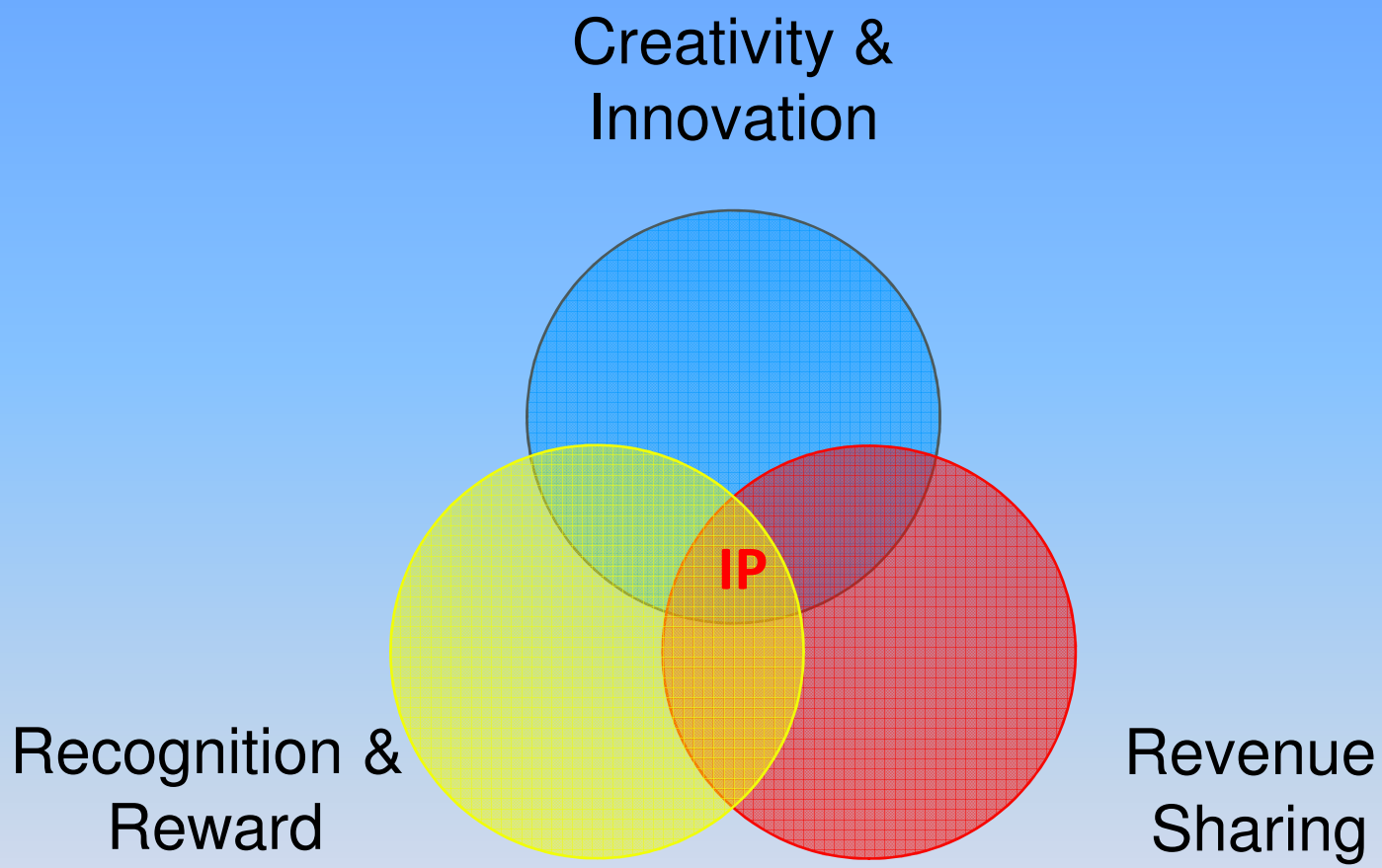

INTELLECTUAL PROPERTY RIGHTS
COPYRIGHTS AND RELATED RIGHTS
INDUSTRIAL PROPERTY RIGHTS
PATENTS
RIGHTS ON DESIGNS
TRADEMARK
PLANT BREEDERS RIGHTS
GEOGRAPHICAL INDICATIONS

# KNOWLEDGE CANOPY




Source- PGanguli©2006

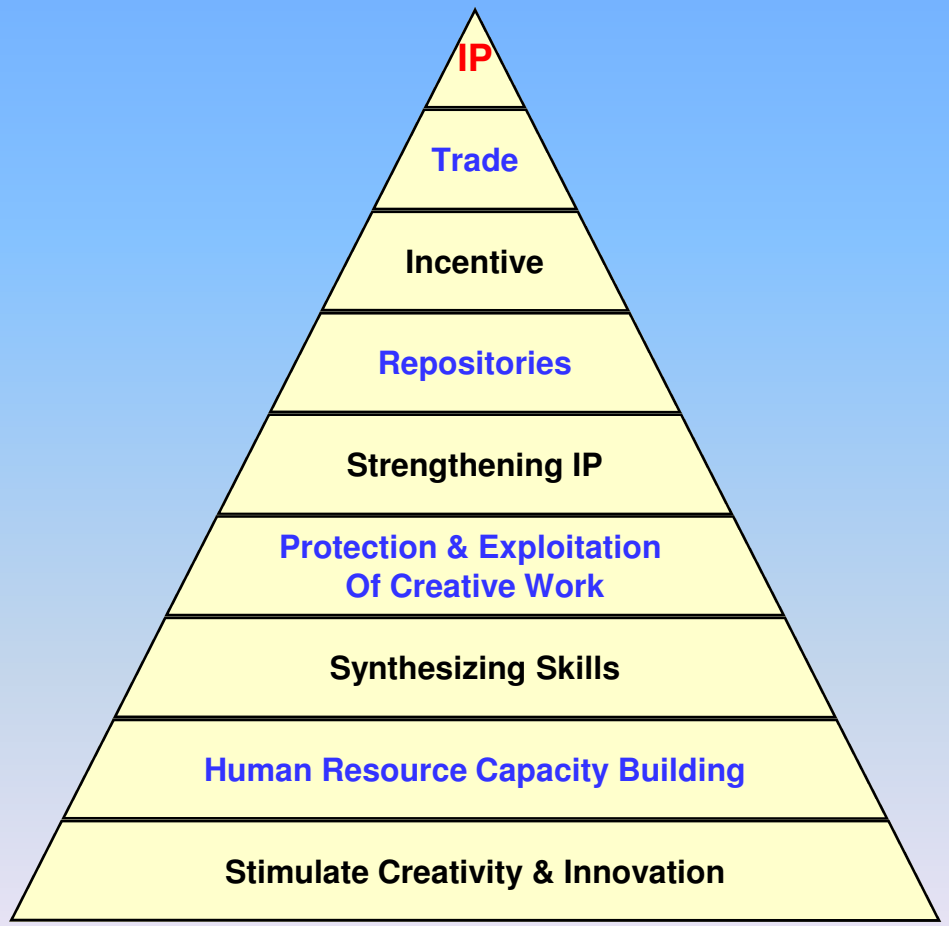
# GUIDING PRINCIPLES

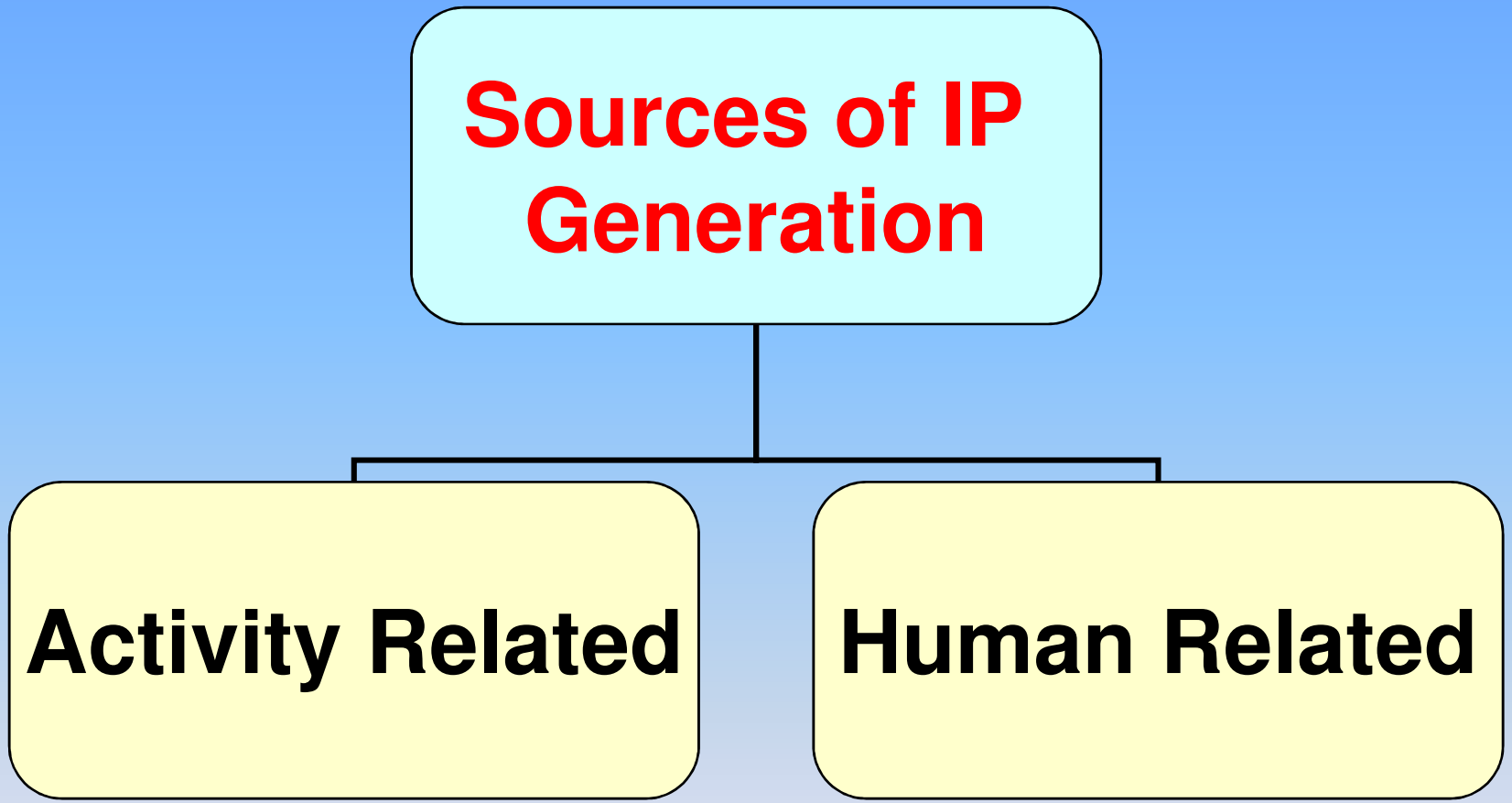



**Key Issue: Ownership of Knowledge**

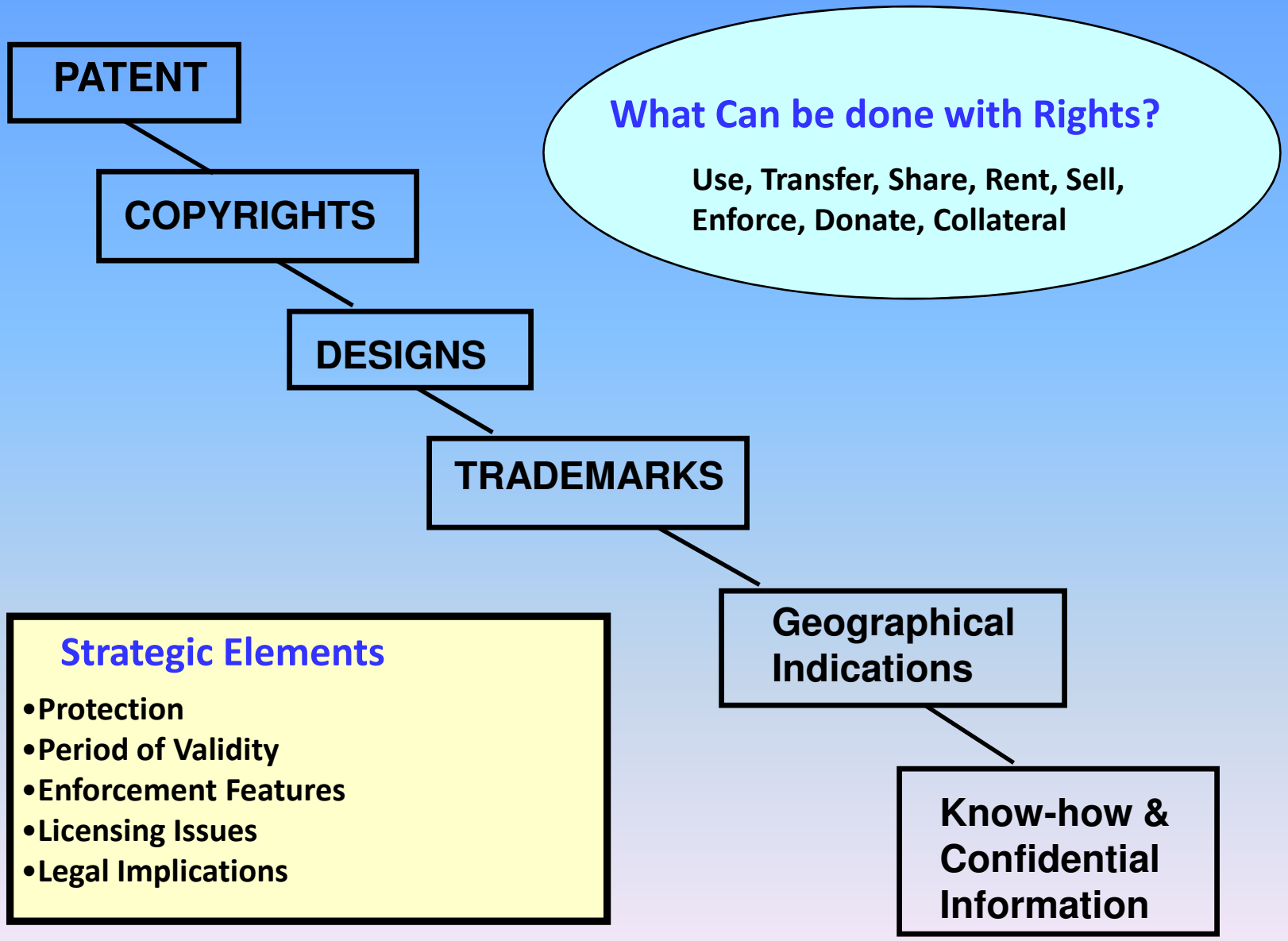
***IPR Plays decisive role***

# OBJECTIVES


IP
Trade
Incentive
Repositories
Strengthening IP
Protection & Exploitation
Of Creative Work
Synthesizing Skills
Human Resource Capacity Building
Stimulate Creativity & Innovation


Sources of IP Generation
Activity Related
Human Related

# TYPES OF IP


PATENT
COPYRIGHTS
DESIGNS
TRADEMARKS
Geographical Indications
Know-how & Confidential Information
What Can be done with Rights?
Use, Transfer, Share, Rent, Sell, Enforce, Donate, Collateral
Strategic Elements
•Protection
•Period of Validity
•Enforcement Features
•Licensing Issues
•Legal Implications

# IP LAWS IN INDIA: CHANGING WITH TIME

- Post –Independence: The Government of India reviewed its IP laws soon after independence, and enacted more development friendly laws.
- Post –TRIPS:

➢ The importance of IPR gathered momentum soon the setting up of the World Trade Organization (WTO) on 1stJanuary 1995.

➢ The IP laws further changed in view of India's commitments under TRIPS under WTO.

- Emerging significance: **INNOVATION**

(Globalization, Economic reforms, Increasing competition, New Technologies, Commercialization of R&D)

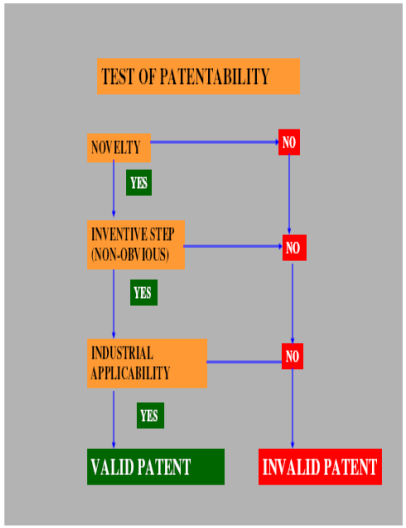
# LAWS CURRENTLY IN FORCE

- the Indian Patents Act 1970 with amendments till 2005
- the Designs Act 2000
- the Trademarks Act 1999
- the Copyright Act 1999
- the Geographical Indications of Goods (Registration & Protection) Act, 1999
- the Semiconductor Integrated Circuit Layout Design Act was enacted in 2000
- the Protection of Plant Varieties and Farmer's Rights Act 1999

# PATENTS

***Patent is an exclusive right granted by the Government/ State for the commercial exploitation of an invention for a limited time and gives the inventor (patentee) an exclusive monopoly of his invention.***

- **Novelty**
- **Inventive step**
- **Industrial applicability**



# THE PATENTS LAW AND PRACTISE

DISCLOSURE OF ADVANCEMENT

INVENTOR

ASSIGNEE OF THE INVENTOR

LEGAL HEIR OF AN INVENTOR/HIS ASSIGNEE


THE PATENT OFFICE

20 YEARS EXCLUSIVE RIGHT ON ADVANCEMENT

Source- ASen©2006

# DESIGNS

- An industrial design is that aspect of a useful article, which is ornamental or aesthetic.

- The owner of the industrial design can prevent unauthorized copying or imitation of the design if it is registered.

- A design must be new or original and industrially reproducible in order to become eligible for protection under industrial design law.

# MARKS

**Work, phrase, symbol, design, sound, smell, colour, product, configuration, group of letters or numbers, or combination of these, adopted and used by a company, to identify its products or services**

# TRADEMARKS

**A trademark is a distinctive sign, which identifies certain goods or services as those produced or provided by a specific person or enterprise.**

**The main characteristics for a trademark are that it must be *distinctive* and should not be *deceptive***

# SERVICE MARKS

Indicate the **source or origin of a service**. For all practical purposes, trademarks and service marks are subject to the same rules of validity, use, protection and infringement.

# PROPERTY MARK

A mark used for denoting that a movable property belongs to a particular person is called property mark.

# GEOGRAPHIC INDICATIONS

**A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin.**

# APPELLATIONS OF ORIGIN

**Are specific types of geographical indications. An appellation of origin is a more precise geographical indication which specifies that the product in question has certain qualities and that those qualities are due essentially or exclusively to its place of origin.**

# LAYOUT DESIGNS IN INTEGRATED CIRCUITS

- A semiconductor integrated circuit is a product having transistors and other circuitry elements, which are inseparably formed on a semiconductor material or an insulating material or inside the semiconductor material and designed to perform an electronic circuitry function.

- In India, the Semiconductor Integrated Circuits Layout-Design Act, 2000 is the prevailing law.

- Registering the layout-design under the Act gives the rights holder the exclusive right to the layout-design and to obtain relief in respect of infringement

# INDIAN PLANT VARIETY AND FARMERS' RIGHT BILL (PVFRB)

*Sue Generic system for the protection of plant varieties; Passed by Lok Sabha on 9 August 2001; yet to be enacted*

**MAIN FEATURES**

Seeks to Establish National Plant Variety and Farmers' Rights Protection Authority (PVFRPA)

**Mandate Registration of plant variety**

- Develop characterization and documentation of registered variety
- Documentation, indexing and cataloguing of farmer's varieties
- Provide compulsory cataloguing facility for all plant varieties
- Ensuring that seeds of all registered varieties are made available to farmers

- Farmer's rights: The act sets out "to recognize and protect the rights of the farmers in respect of their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties "as well as
- Commercial breeders: "to protect plant breeders' rights to stimulate investment for research and development, both in the public and private sector, for the development of new plant varieties."
- Directly related to the innovation in the field of agriculture and conservation of biological resources

# COPYRIGHTS

- Exclusive Legal Rights on Creativity
- Bundle of Rights (*Moral & Economic*)
- Protects *Originality of Expression* and *not ideas*
- National in Nature

**Domain-** ***Literary and Artistic works***

**Writings, Music, Works of the fine arts; paintings and sculptures,**

**Technology based; computers programs and electronic databases**

# CONFIDENTIAL INFORMATION / KNOW- HOW

- Confidential information is any information generally not known or readily accessible to persons in the field and is of commercial value that is being prevented from being disclosed by the owner of the information e.g. the list of customers

- Know –how is a form of confidential information that may not have the benefit of patent protection e.g. aggregation of known processes, accumulation of data, a secret formulation

- No specific law on trade secrets. Protected under the contract law.

# TRADE SECRET

It is a formula, pattern, physical device, idea, process, compilation of information or other information that provides the owner of the information with a competitive advantage in the marketplace, and is treated in a way that can reasonably be expected to prevent the public or competitors from learning about it.

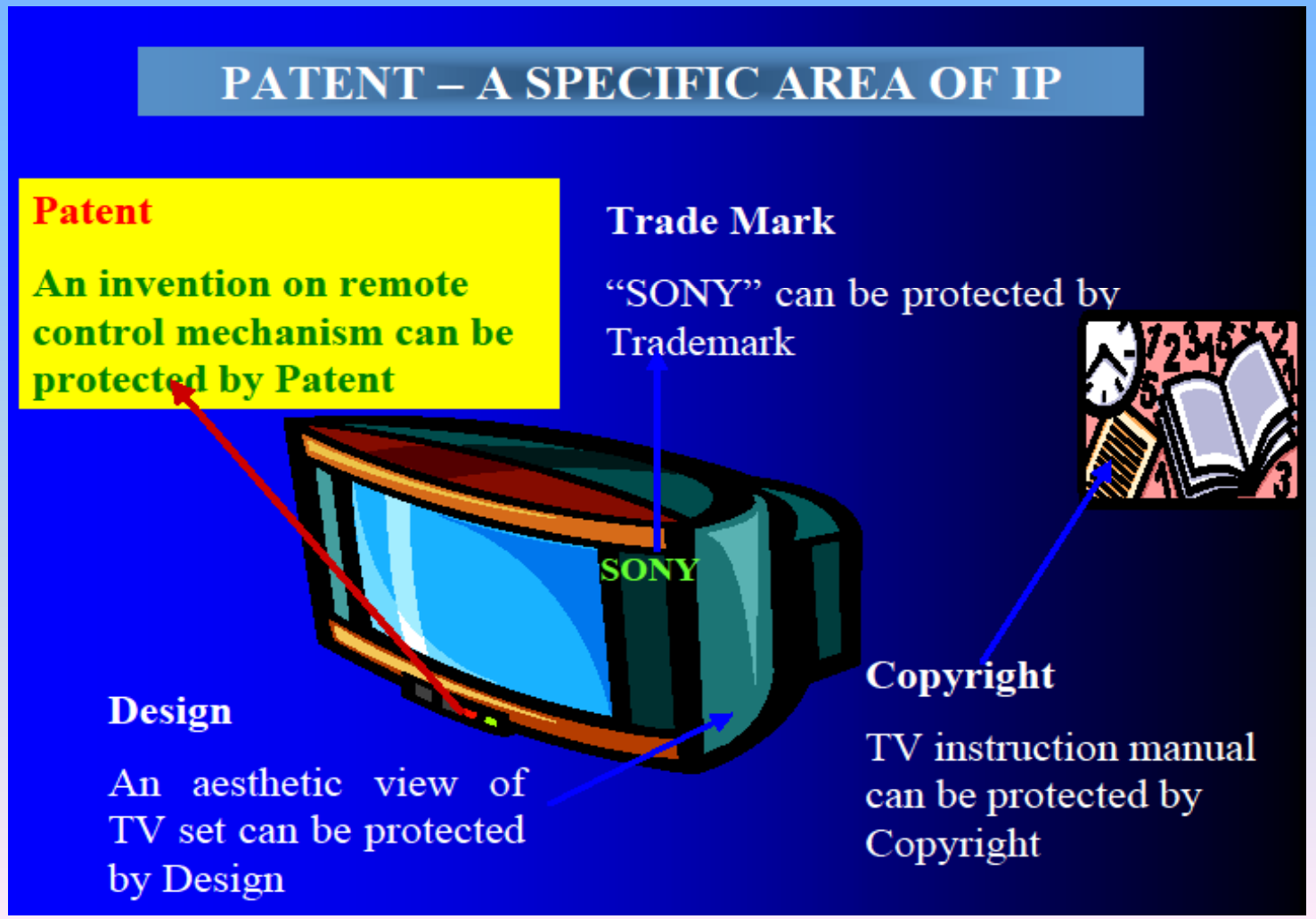
**In Indian we have no legal provisions to protect trade secrets for the time being.**

# WIPO BODY

**Established by a convention signed at Stockholm on July 4, 1967 administers various international treaties offering protection to intellectual properties all over the world.**

| | |
|---|---|
| BERNE CONVENTION | (Copyright) |
| MADRID AGREEMENT | (Trademark) |
| HAGUE AGREEMENT | (Industrial Designs) |
| PATENT CO-OPERATION TREATY | (Patent) |
| LISBON AGREEMENT | (Geographical Indication) |
| WIPO PERFORMANCE &PHONOGRAMS TREATY | (Related Rights) |
| UPOV CONVENTION | (Plant Breeder's Right) |
| | |

# DETERMINING NOVELTY, INVENTIVE STEP & UTILITY OF INVENTIONS



# INTELLECTUAL PROPERTY PROTECTION

- **Is it new?** — **Look for Patent**
- **Who wants it?** — **Look for Market**
- **Does it work?** — **Look for Technical advantage**

**"It is not the strongest of the species that survive, not the most intelligent, but the one most responsive to change"**

***Charles Darwin***

# PATENTS

# PATENTS

Patent is an exclusive right granted by the Government/ State for the commercial exploitation of an invention for a limited time and gives the inventor (patentee) an exclusive monopoly of his invention. A patent therefore is a property, which likes any other property, movable or immovable, may be bought, sold, assigned or licensed. Patent requires the inventor to disclose the invention and to define the boundary of the patented invention so that the public at large can practice the invention on expiry of the patent. Thus, patents are **PUBLISHED** and are not secret. "Invention" means a solution to a specific problem in the field of technology. For an invention to qualify for patent protection it must fulfill the following conditions

- Novelty
- Inventive step
- Industrial applicability
- Not excluded

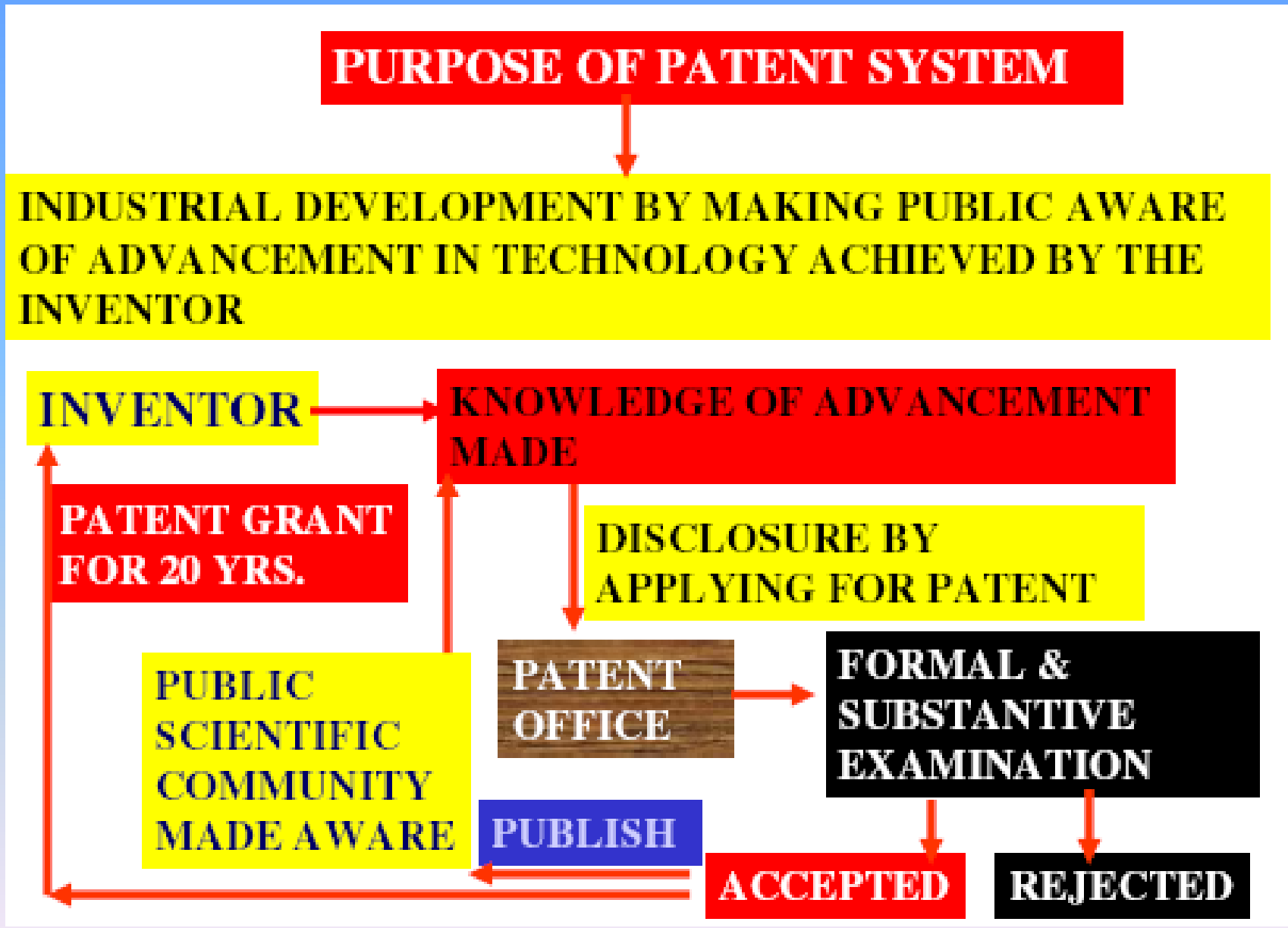
The invention comes into public domain after the expiry of the term of the patent that is generally twenty years from the date of filing of the application. Regular payment of renewal fees is required after the 5th year (i.e. the 5th year is the lowest fee, gradually rising to the 19th year being the highest fee).

# WHAT IS A PATENT

- A patent is an exclusive territorial rights conferred by the state to the inventor/ applicant to exploit his/her invention for commercial benefit for a limited period in consideration of his/her complete disclosure of the invention

- It is a negative right, it prevents other from using this right without the consent of the patentee.

- The patent is granted as per the Patents Act, 1970 as amended by the Patents (Amendment Act, 2005)




Source: asen2006

# PATENTEE

A patentee is the applicant for a patent for the time being entered in the Register of Patents maintained in the Patent Office and is the grantee or proprietor of the invention disclosed in the said patent.

# PATENTEE

**An applicant for the patent- Maintained in the Patent Office**

- Disclosure of Information
- Payment of Fees
- Watch Dog

# RIGHTS OF PATENTEES

## FOR A PRODUCT PATENT

PREVENT OTHERS FROM


## FOR A PROCESS PATENT

PREVENT OTHERS FROM


Source: asen2006

# PATENTABLE INVENTION [SECTION 2 (1) J]

Must be a process or a product or a combination of thereof

**AND**

Must satisfy three criteria cumulatively

- Must be Novel
- Must involve an Inventive Step
- Must be Industrially Applicable

# PATENTABILITY CRITERIA AND PATENTABLE SUBJECT MATTER

# ONLY INVETIONS ARE PATENTABLE

***"An invention means a new product or process involving an inventive steps and capable of industrial application" (S.2(1)(j)***

**Where**

***Inventive step*** *means a feature that makes the invention not obvious to a person skilled in the art (S.2(1)(ja)*

***And***

***Capable of industrial application,*** *in relation to an invention, means that the invention is capable of being made or used in an industry (s.2(1)(ac)*

# CRITERIA

- Novelty
- Inventive step
- Industrial applicability

# NOVELTY

- Which has not be disclosed, in the prior art

- Not publicly known anywhere in the world prior to filing the application for a patent

# BASIC POINTS ABOUT NOVELTY

- Novelty is determined before inventive step because the creative contribution of the inventor can be accessed only by knowing the novel elements of the invention.

- Any prior document, in order to be novelty destroying, must contain an enabling disclosure.

- The anticipatory disclosure must be entirely contained within a single document. In case more than one document is cited, each document should stand on its own.

# HOW THE NOVELTY CAN BE DESTROYED?

- **Prior publication**
- **Prior claim**
- **Prior public knowledge or use**
- **Prior public working**

# CASE STUDY

**STUDY-**

- See for instance ( 1956 RPC 87 Fermento Appln) the inventor gifted his ball-pen to his three friends who used them before the date of filing of the patent application. Subsequently the validity of the Patent was challenged on the ground of prior publication and working. The court held that since the inventor gifted his pens to his friends who were free to use them in any manner they wished and there was no restriction regarding the use of these pens, such prior use destroy novelty. *Prior publication*

# CASE STUDY

**STUDY-**

- If the prior publication is contained in a document, it may not be necessary that members of the public should have actually read the document. It is enough **if the document is accessible to the public** without much trouble (*Lallubhai Chakubhai v. Chimanlal Chunilal & Co. A.I.R. 1936 Prior publication Bom. 1999*

# INVENTIVE STEP

**A feature that makes the invention not obvious to a person skilled in the art**

Some indications of non-obviousness are listed below

- A surprising result
- The solution to a long-standing problem
- A great technical progress
- Commercial success linked to the merits of the invention
- The fulfilment of a long-felt need

# OBVIOUSNESS

When the alleged invention does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art it will be regarded as obvious if a claim to it would inhibit the activities of a skilled workman to carry out routine modifications of what is already in the public domain.

# OBVIOUSNESS

- The test of obviousness does not mean that an invention has to be technically complex. An invention can be very simple also.

Prior Art

Invention ::This paper clip patented by Johan Vaaler in 1901.(US Patent No. 675,761 June 4, 1901 )

Source- MThakur©2008

# WHO IS THE SKILLED PERSON?

- An ordinary practitioner aware of what is common general knowledge in the art at the relevant date.
- Having access to everything in the state of the art
- Need not possess inventive capability and generally would not engage in creative thinking.
- Can be expected to look for suggestions in neighboring field where similar problem may be present.
- Cannot be expected to perform scientific research in areas not yet explored.
- Follows normally the path indicated in the state of the art.

# SOME EXAMPLES OF LACKING INVENTIVE STEP

- When invention lies only in providing equivalents (mechanical,electrical or chemical) to the known art. For example, *use of hydraulic motor instead of electric motor in a pump.*
- When the prior art is incomplete and the invention lies in "filling the gap". For example, *invention :building structure made from aluminium // Prior art ---a structure of light weight material but not aluminium.*
- When the invention consists of a new use of well-known material employing the known properties of that material. For example, a washing composition containing known detergent having property of lowering the surface tension of water;the property being known as the essential one for detergents.

# SOME EXAMPLES OF LACKING INVENTIVE STEP

(i) A chair of eight leg for better support

(ii) A chemical reaction where the active reagent having same group is changed with different substitutes

(iii) Purification/treatment method with different solvent

(iv) A fan with six blade

# INDUSTRIAL APPLICATION

- Can be made
- Can be used in at least one field of activity
- Can be reproduced with the same characteristics as many times as necessary

# INDUSTRIAL APPLICABILITY

- An invention for a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body is not taken to be capable of industrial application.

- Parts /pieces of the human or animal body to be used in transplants are objected as not being capable of industrial application.

# UNITY OF INVENTION

***"the claim or claims of a complete specification shall relate to a single invention or to a group of inventions linked so as to form a single inventive concept……" (S.10(5)***

It means that all claims in the application for patent must refer to the same inventive idea i.e. they must all share one inventive concept.

# DIFFERENT CATEGORIES OF INDEPENDENT CLAIMS STATING UNITY OF INVENTION:

- Product, process for its manufacture and use of the product
- Process and apparatus for carrying out the process
- Product, process for its manufacture and apparatus for carrying out the process

# SUFFICIENCY OF DISCLOSURE

*"Every complete specification shall –*

- Fully and particularly describe the invention and its operation or use and method by which it is to be performed;
- Disclose the best method for performing the invention which is known to the applicant and for which he is entitled to claim protection; and……."(s.10(4)

# DO'S AND DON'TS OF PATENTS

Patents give patentee (proprietors) the right to take legal action to prevent other people from exploiting a patented invention without the proprietor's permission. A person who develops the invention does not need a patent for commercializing it. He already has the right to commercialize the invention if someone else does not already protect it. But in the event of the invention not being patented he does not have legal right to stop others from working the said invention

- The grant of a patent for an invention does not guarantee the merit or any other commercial value of the invention disclosed. The state (country), which grants the patent, does not also guarantee the validity of the patent granted.

- The government (State) does not give any financial or any other award or assistance to the inventor/patentee in granting the patent.

# PATENTABLE SUBJECT MATTER

# PATENTABLE SUBJECT MATTER

- Those which are not inventions (S.3)
- Invention relating to atomic energy (S.4)
- Inventions where only process is patentable (S.5(1)

# WHAT ARE NOT INVENTIONS

- **Section 3(a)**

  **An invention which is frivolous or which claims anything obvious contrary to well established natural laws.**

- **Section 3(b)**

  **An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;**

- **Section 3(c)**

  **The mere discovery of a scientific principle or the formulation of an abstract theory or discovery or any living thing or non-living substances occurring in nature;**

➢**Section 3(d)**

**The mere discovery of a any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant:**

➢**Section 3(e)**

**The substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substances:**

➢**Section 3(f)**

**The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;**

- **Section 3(h)**

  A **method of agriculture or horticulture;**

- **Section 3(i)**

  **Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human being or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;**

- **Section 3(j)**

  **Plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;**

- **Section 3(k)**

  A **mathematical or business method or a computer program per se or algorithms;**

- **Section 3(l)**

  A **literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television production;**

- **Section 3(m)**

  A **mere scheme or rule or method of performing mental act or method of playing games;**

- **Section 3(n)**

  **A presentation of information;**

- **Section 3(o)**

  **Topography of integrated circuits;**

- **Section 3(p)**

  **An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components;**

# INVENTIONS RELATING TO ATOMIC ENERGY (S.4)

***No patent shall be granted in respect of an invention relating to atomic energy falling within subsection (1) of section 20 of atomic energy Act, 1962***

eg. Inventions relating to compounds of Uranium, Beryllium, Thorium, Plutonium, Radium, Graphite, Lithium and more as notified by Central Govt, from time to time.

# INVENTIONS WHERE ONLY PROCESS IS PATENTABLE (S.5 (1)

- Inventions claiming substances intended for use, or capable of being used, as food, or as medicine or drug.

- Inventions relating to substances prepared or produced by chemical processes.

**It also implies that GMO is a patentable subject matter, but the product is not patentable but the biological process employed for that is patentable.**

# PATENT DOCUMENTS AND DATABASES

# PATENT DATABASES

- Source of detailed information about a specific invention
- Source of information about the field of invention
- Review of important technology
- Determining the major players in a field
- Enabling forward planning for commercialisation

# WHEN TO ACCESS PATENT INFORMATION?

**Before the start of R & D Project :**

- Stops in re-inventing the wheel
- Gets a clear and broad picture of the state of art
- Lists shortcomings/drawbacks in the state of art

# WHEN TO ACCESS PATENT INFORMATION?

## During the R & D Phase

- Lists solution to the technical problem
- Establishes the novelty

# WHEN TO ACCESS PATENT INFORMATION?

**After the completion of R & D Project :**

- Helps in drafting the Patent application

- Helps in either broadening or narrowing down claims

# WHY IS A PATENT INFORMATION IS IMPORTANT?

## General Reasons

## Technical Reasons

- transferring of technology
- Stopping reinventing the wheel
- detail working of invention

# WHY TO ACCESS PATENT INFORMATION?

- largest and most comprehensive source
- commercial, legal and technical information at one place
- to avoid infringement suit
- to stop re inventing the wheel

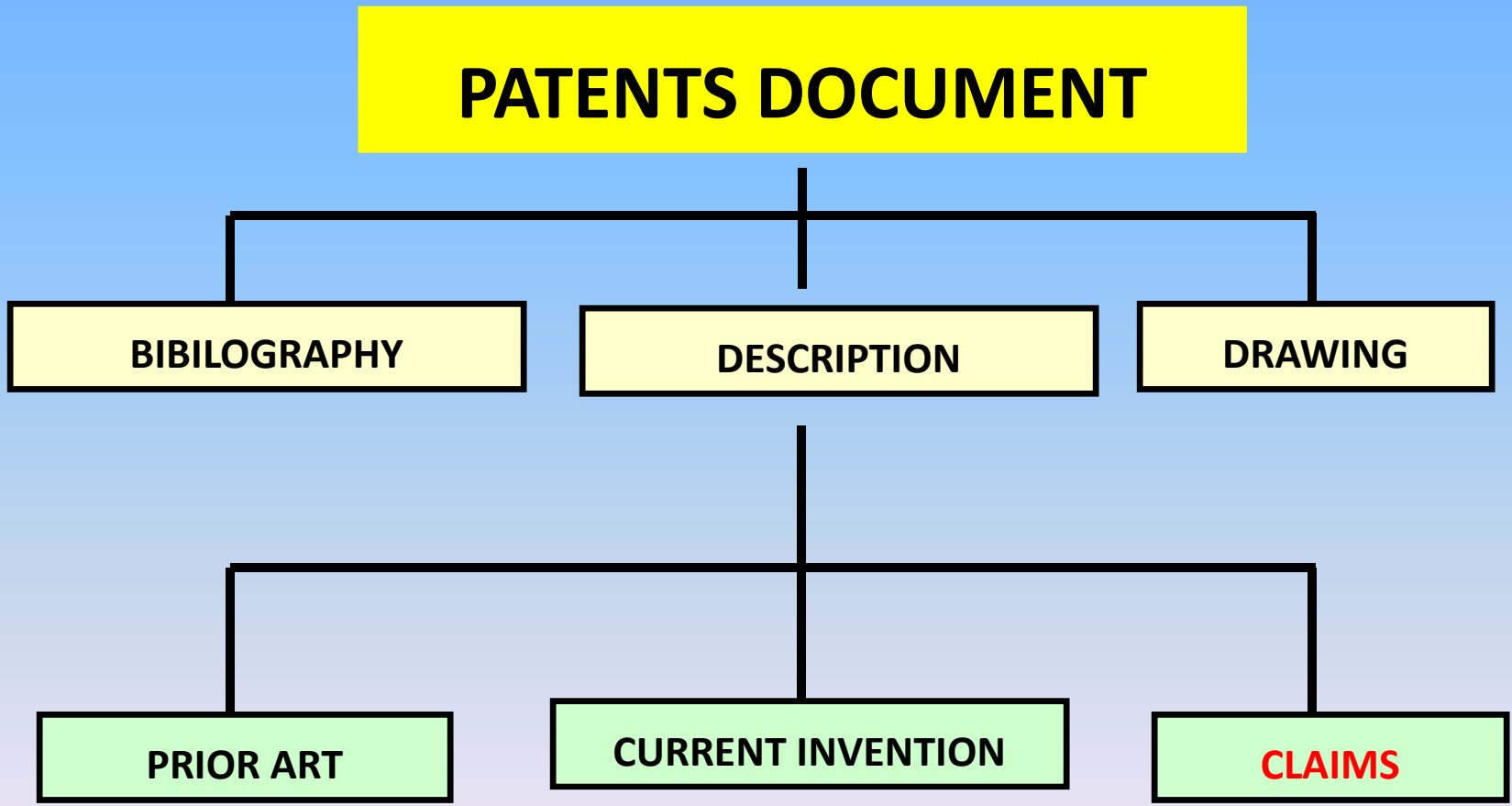
# HOW TO ACCESS PATENT INFORMATION?

- In-house Search
- On-line Search
- Free access on Internet
- Access Methodology

# WHICH ARE THE SOURCES FOR PATENT INFORMATION?

- Commercial Vendors
- Internet Based
- CD-ROM based

# WHAT DOES A PATENT DOCUMENT CONTAIN?



# WHAT DOES A PATENT DOCUMENT CONTAIN?

- Bibliographic information
- Abstract
- Description of invention
  - Prior-art information
  - Defective short comings in the prior art
  - Complete details of the invention
- Drawing and workable examples
- List of claims by the patentee

# PATENT HAS THREE MAIN SECTIONS

(i) a **cover page** which presents bibliographic information,

(ii) a **specification** which describes the invention, and

(iii) **claims**, which define the metes and bounds of the patentee's right.

# COVER PAGE

- Bibliographic information
- No legal importance
- Historical facts
- Identifying elements
  - Application filing date
  - Serial number

# BIBLIOGRAPHIC INFORMATION

- **INID Codes** (Internationally Agreed Number for identification of Data Elements)
- **IPC Codes** (International Classification Codes)

# BIBLIOGRAPHIC INFORMATION

- Title of invention
- Abstract of invention
- Countries
  - Country of inventor
  - Country of applicant
  - Country of priority
  - Country of grant
  - Designated Countries

# BIBLIOGRAPHIC INFORMATION

## Number and Dates

- Application number and date
- Priority number and date
- Patent number and date

# BIBLIOGRAPHIC INFORMATION

Inventor Name (s)

- Who invented

Applicant Name (s)

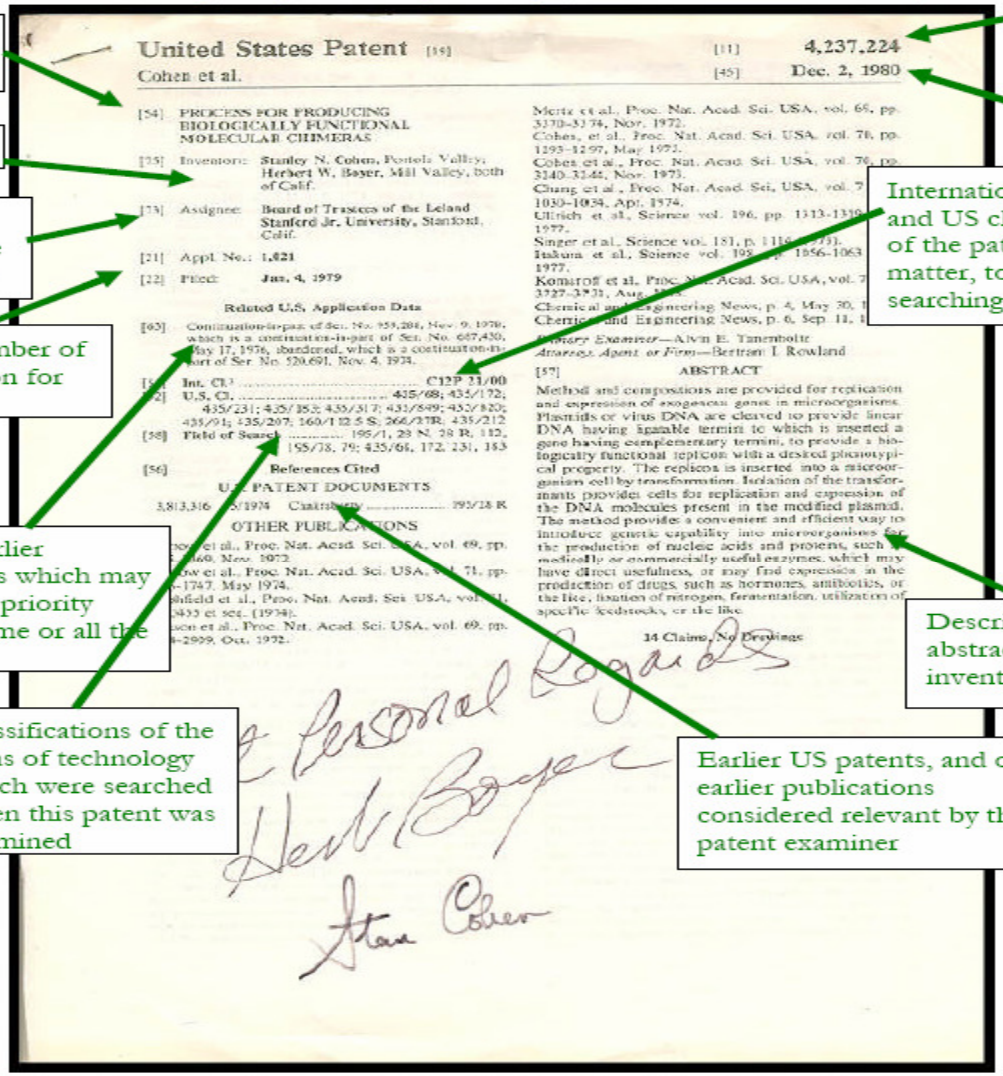
- Who applied

# BIBLIOGRAPHIC INFORMATION

- Kind of Publication
  - Published before grant
    - With a search report
    - Without Search report
  - Published after grant
- Language of Publication
- Classification codes
  - International Patent Classification Codes
  - National Classification Codes

# The front page of a US patent document

*This is the front page of a patent issued to Herbert Boyer and Stan Cohen for their breakthrough in genetic engineering (described in Module Two).*



United States Patent [19]
Cohen et al.

[11] 4,237,224
[45] Dec. 2, 1980

[54] PROCESS FOR PRODUCING BIOLOGICALLY FUNCTIONAL MOLECULAR CHIMERAS

[75] Inventors: Stanley N. Cohen, Portola Valley; Herbert W. Boyer, Mill Valley, both of Calif.

[73] Assignee: Board of Trustees of the Leland Stanford Jr. University, Stanford, Calif.

[21] Appl. No.: 1,821

[22] Filed: Jan. 4, 1979

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 955,284, Nov. 9, 1978, which is a continuation-in-part of Ser. No. 607,430, May 17, 1976, abandoned, which is a continuation-in-part of Ser. No. 520,691, Nov. 4, 1974.

[51] Int. Cl.³ ..... C12P 21/00
[52] U.S. Cl. ..... 435/68; 435/172; 435/231; 435/253; 435/317; 435/849; 435/820; 435/91; 435/207; 260/112.5 R; 260/3.5R; 435/212
[58] Field of Search ..... 195/1, 28 N, 28 R, 172, 195/3.5, 79; 435/68, 172, 231, 253

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Chemical and Engineering News, p. 4, May 30, 1...
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*Primary Examiner*—Alvin E. Tanenholtz
*Attorney, Agent, or Firm*—Bertram I. Rowland

[57] ABSTRACT

Method and compositions are provided for replication and expression of exogenous genes in microorganisms. Plasmids or virus DNA are cleaved to provide linear DNA having joinable termini to which is inserted a gene having complementary termini, to provide a biologically functional replicon with a desired phenotypical property. The replicon is inserted into a microorganism cell by transformation. Isolation of the transformants provides cells for replication and expression of the DNA molecules present in the modified plasmid. The method provides a convenient and efficient way to introduce genetic capability into microorganisms for the production of nucleic acids and proteins, such as medically or commercially useful enzymes, which may have direct usefulness, or may find expression in the production of drugs, such as hormones, antibiotics, or the like, fixation of nitrogen, fermentation, utilization of specific feedstocks, or the like.

14 Claims, No Drawings

Title of the invention

Patent number

Date of issue

Inventors

Assignee (owner of the patent right)

International (IPC) and US classifications of the patent's subject matter, to assist in searching

Date and number of the application for this patent

Data on earlier applications which may give earlier priority dates to some or all the claims

Descriptive abstract of the invention

Classifications of the areas of technology which were searched when this patent was examined

Earlier US patents, and other earlier publications considered relevant by the patent examiner

In this format, the front page does not give the details of the claim, but provides information about the claimed invention in the form of a descriptive abstract. The subject matter of the claims is generally covered in the abstract, but the abstract does not have the same legal effect as the claims themselves. Further pages include a description of the invention, with an account of the background to the invention, including relevant prior art (pre-existing technology), and a detailed description of the best way known of putting the invention into practice.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 May 2005 (12.05.2005)

PCT

(10) International Publication Number
WO 2005/042570 A1

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(21) International Application Number: PCT/US2004/035839

(22) International Filing Date: 27 October 2004 (27.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| 60/514,740 | 27 October 2003 (27.10.2003) | US |
| 60/525,222 | 26 November 2003 (26.11.2003) | US |
| 60/561,662 | 13 April 2004 (13.04.2004) | US |

(71) Applicant *(for all designated States except US)*: **VERTEX PHARMACEUTICALS INCORPORATED** [US/US]; 130 Waverly Street, Cambridge, MA 02139-4242 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LIN, Chao** [US/US]; 4 Dean Road, Winchester, MA 01890 (US). **LIN, Kai** [CN/US]; 153 Hawthorne Road, Waltham, MA 02451 (US).

(74) Agent: **MCMILLIAN, Nabeela, R.**; Marshall, Gerstein & Borun LLP, 6300 Sears Tower, 233 South Wacker Drive, Chicago, IL 60606 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 2005/042570 A1

(54) Title: HCV NS3-NS4A PROTEASE RESISTANCE MUTANTS

(57) Abstract: The present invention is directed to mutants of HCV NS3/4A protease. More particularly, the present invention identifies mutant of HCV NS3/4A protease that are resistant to drug treatment.

# SPECIFICATION

- Description of the invention
- Disclosure
- Aid to interpreting the scope of claims

# SPECIFICATION LAYOUT

(a) title of the invention;

(b) background of the invention;

(c) summary of the invention;

(d) description of the drawing;

(e) detailed description of the invention;

(f) sequence listing; and

(g) claims

# WHO ARE READERS OF PATENT SPECIFICATION

- PATENT EXAMINERS
- PATENT ATTORNEYS/LAWYERS
- PROSPECTIVE INVENTORS
- SCIENTISTS/ENGINEERS-R&D PERSONNEL
- STUDENTS/RESEARCH SCHOLARS
- ENTREUPRENEURS/CORPORATES WATCHING COMPETITIVE BUSINESS ACTIVITIES
- JUDICIARY-INFRINGEMENT/VALIDITY ISSUES

Source: asen2006

# BACKGROUND OF THE INVENTION

- Typically drafted for a jury audience
- Selected art in the field is discussed to emphasize differences with the current invention
- Point out the needs for the current invention

# SUMMARY OF THE INVENTION

- Distinct from the abstract
- Meant to discuss the invention (i.e., the claims) rather than the disclosures as a whole
- Often, discuss advantages of the invention or how it solves the problems existing in the art, such as those presented in the Background of the Invention

# DETAILED DESCRIPTION OF THE INVENTION

- The meatiest section of the patent
- Purpose: adequately and accurately describe the invention
- Generally two section:
  - (i) general explanation of the invention and how to practice it
  - (ii) specific examples of how to practice the invention

# GENERAL EXPLANATION OF THE INVENTION

- Invention is described in its broadest sense
- Shows the inventors have a broad view of the scope of the elements
- Preferred embodiments of invention described
- Definitions of key terms extremely important in interpreting the scope of claims.

# SPECIFIC EXAMPLES: HOW TO PRACTICE INVENTION

- Patent application does **NOT** require examples
- Examples often assist in showing patent ability
- Examples may or may not have been performed by the inventors
- "Working" examples – completed undertaking
- "Prophetic" examples are hypothetical undertaking
- Typically, examples demonstrate practice of one or more specific embodiments of the invention.

# SEQUENCE LISTING

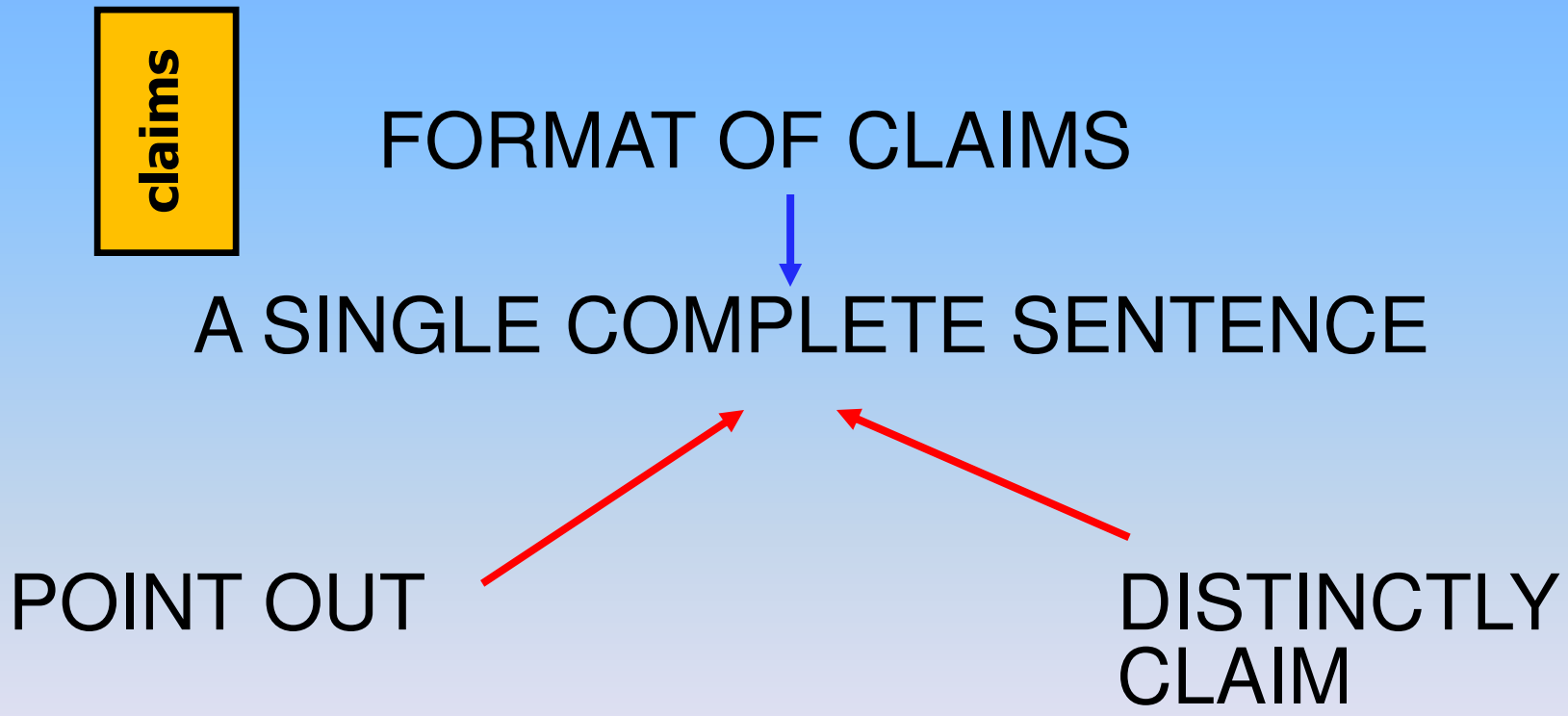
- If necessary, may be present as third section
- Including every nucleic acid molecule that is at least 10 nucleotides
- An every disclosed protein that is at least 4 amino acids

# CLAIMS…..

- Most important part of a patent
- The claims must “particularly point out and distinctly claim the subject matter which the applicant regards as his invention”
- Reasoning: possible infringers must be able to understand what is and is not protected
- At least one claim in a patent

# CLAIMS…..

- PLACEMENT OF CLAIMS:
  **AT THE END OF THE SPECIFICATION**



# CLAIMS…..

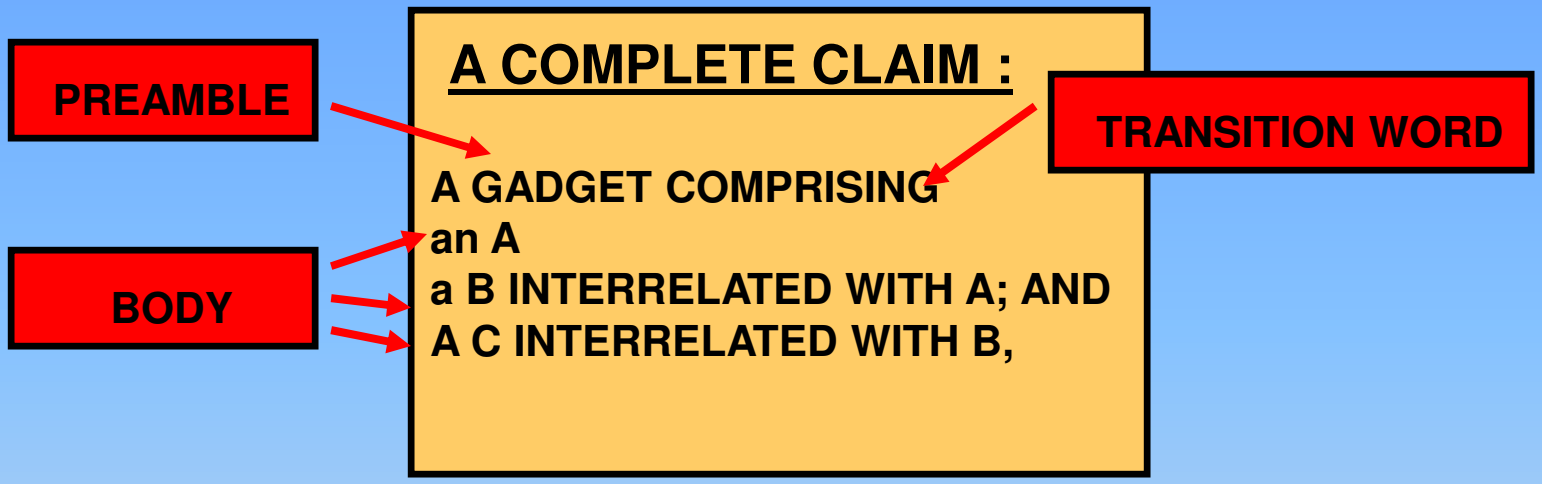
- Claim presented in two parts:
  - the *preamble*
  - the *body*

- *Preamble*. *Introductory statement names the thing that is to be claimed*

- *Body*. Defines what elements or steps of the named thing are.

- A transition word or phrase in between

# CLAIMS…..




## WAY OF WRITING:

A GADGET COMPRISING
an A
a B;
a C;
MEANS INTERERELATING A WITH B;
MEANS INTERERELATING B WITH C,

## WAY OF WRITING:

A GADGET COMPRISING
an A ;
a B;

MEANS INTERERELATING A WITH B;
A C; AND
MEANS INTERERELATING B WITH C

# TWO FLAVORS OF CLAIMS

*Independent claim*: Stands alone

- Includes all the necessary limitations
- Does not depend on or include limitations from any other claim

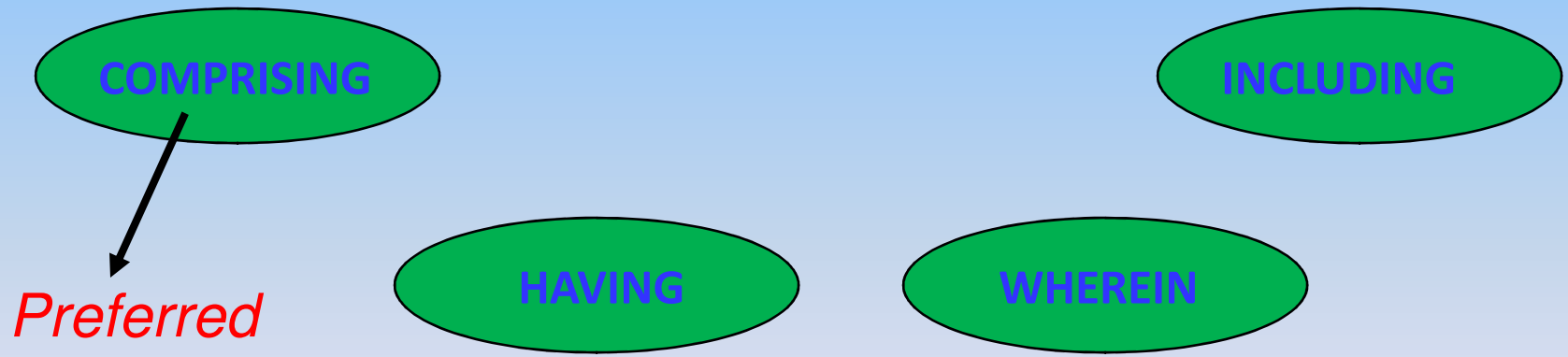
*Dependent claim*: refers back to another claim or claims

- Further limits another claim or claims
- Includes all the limitations of the claim incorporated by reference

# HOW WORDS IN A CLAIM CAN BE CRITICAL

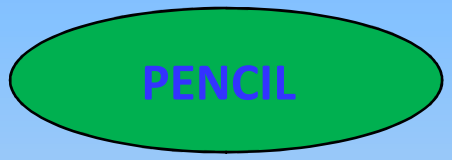
OPEN ENDED WORDS: COMPRISES

POSSIBLE EQUIVALENTS

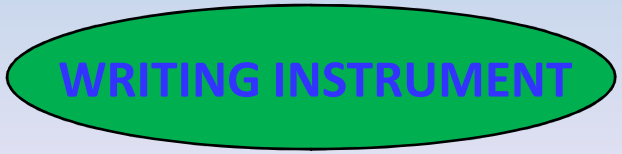


# HOW DO YOU MAKE GENERIC THE PREAMBLE OF THE CLAIM

Claim Worded:

A 

having an erasure means at one end

A 

having an erasure means at one end

WHEN YOU SAY “PENCIL” IT IS ONLY PENCIL

WHEN YOU SAY WRITING INSTRUMENT

IT WOULD COVER-

**Wood pencil, mechanical pencil,**

**Possibly pens with erasing means**

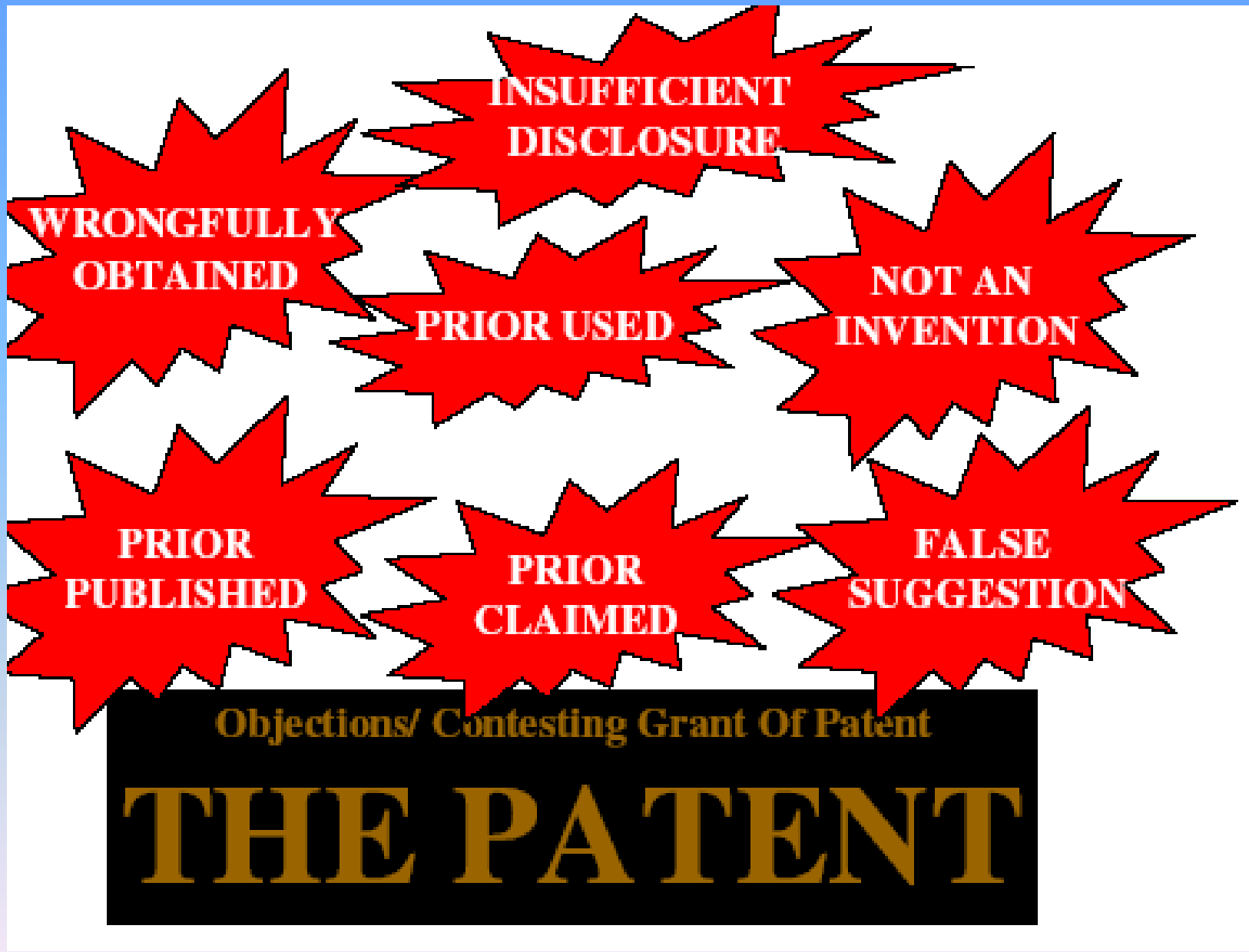
# TRANSITION WORD OR PHRASES

- Commonly used – very distinct meanings:

- "*Comprising*" open-ended language, means
  - The claim encompasses all the elements listed
  - But does not exclude additional, unnamed elements

"*Consisting of*" means the device (or method) has the recited elements and no more

"*Consisting essentially of*" : meaning intermediate to comprising and consisting of not often used




Source: asen2006

# PATENT FEATURES

# IS IT NECESSARY TO FILE AN APPLICATION ?

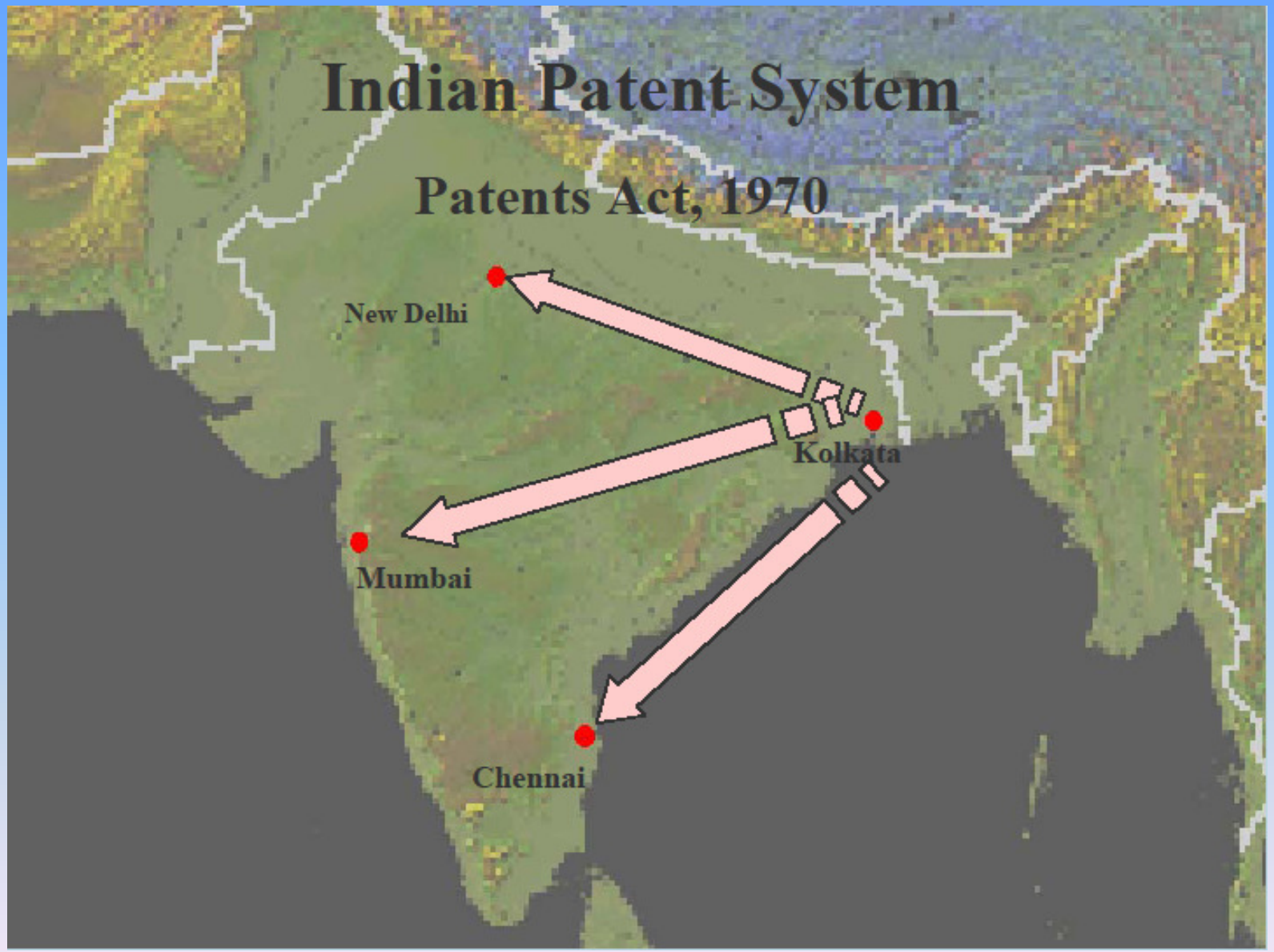
- An inventor can secretly exploit his/her invention exclusively without disclosing his/her invention to anybody
- **BUT ?** – There is a great risk involved by way of leaking out or development of technology by others, **LOSS** of exclusivity when investment is high
- **SO,** it is always beneficial for the inventor to file an application for patent

# BENEFITS OF PATENT

- Provide threshold knowledge for young and promising scientists in their research and development
- The burden of duplication of the invention is avoided: it saves further spending of time and money ; **STOPS WASTAGE OF RESEOURCES**

# BENEFITS OF PATENT

- Any interested person may buy the Patent, wherein the Patent becomes a nice tool for the transfer of technology
- Patent provides protection to the Patentee wherein, if the Patent is infringed, the Patentee may seek the legal remedies. Thus Patent is a form of social security to an inventor.
- Once, the life of the patent is over, any person may freely, without paying any royalty to the Patentee, may enjoy the invention.


Indian Patent System
Patents Act, 1970
New Delhi
Kolkata
Mumbai
Chennai

# WHO CAN APPLY?

- The inventor either alone or jointly with another person
- His/Their Assignee
- Legal representative of deceased inventor or assignee

# WHEN TO FILE A PATENT APPLICATION

**Filing should be made immediate after the invention is developed for commercial working**

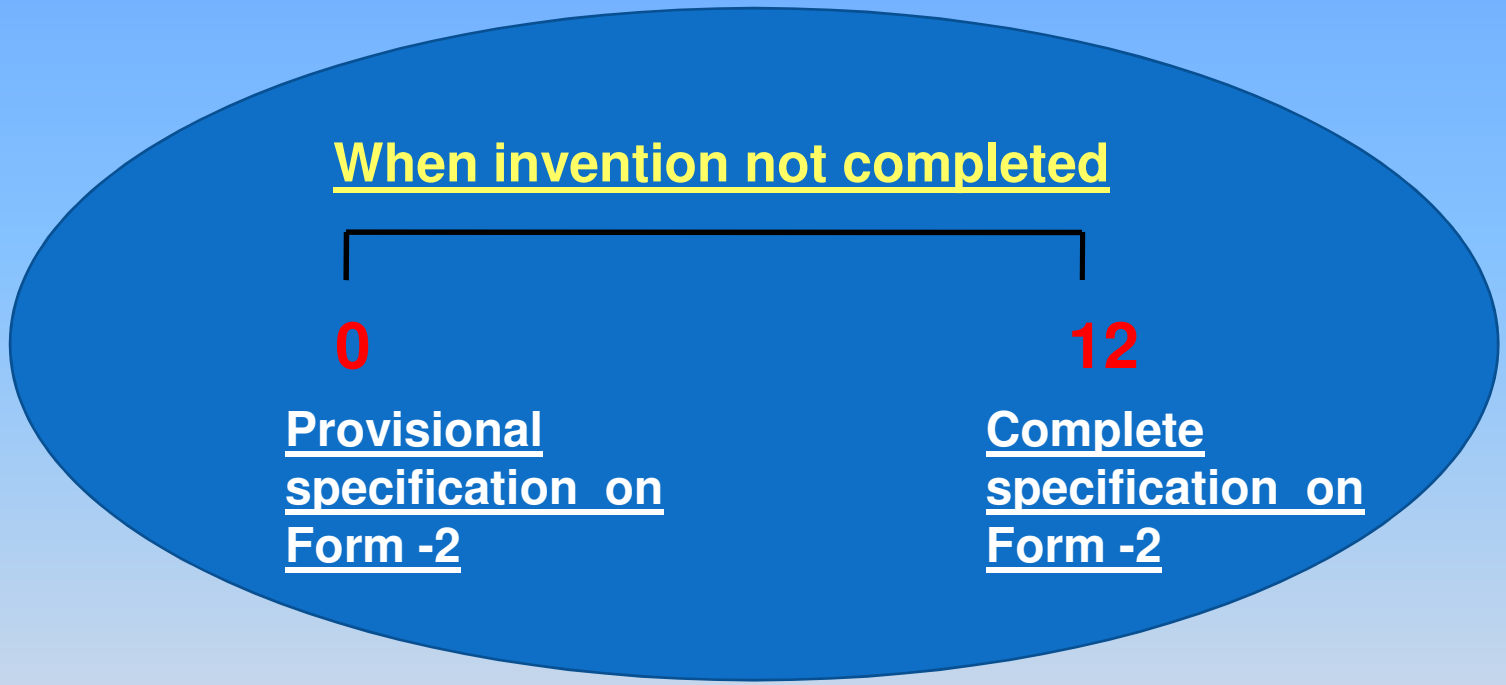
**Delay in filing may involve certain risks:**

- Other invention of substantially same nature may take advantage of priority, depriving the true and first inventor
- An inadvertent publication of invention by inventor or others may damage the novelty of invention
- Patent should be filed before any kind of publication or commercial using or communication to others

# TYPES OF APPLICATION FOR PATENT

- An ordinary application for Patent (under section 7 of the Act)
- Convention application for Patent (under section 7 and 135 of the Act)
- An application for Patent of addition under Section 54 of the Act (granted for improvement of already patented invention for the un expired term of the main patent)
- National Phase applications under PCT

# ORDINARY APPLICATION FOR PATENT




{Provisional specification - to describe only the nature of invention drawing (s) when necessary for better explanation}

# ORDINARY APPLICATION FOR PATENT

**When invention is completed**

1. Application on Form 1
2. Complete specification on Form 2
3. Appropriate Fee
4. Proof of right to make the application
5. Power of authority
6. Drawings
7. Abstract

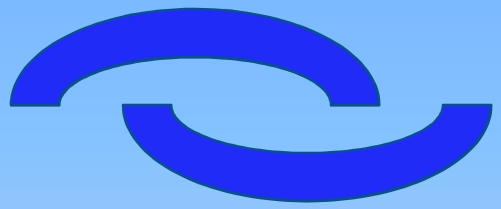
**{Complete specification - to describe the nature of invention and the manner in which it is to be performed and contains claim(s)}**

# COMPLETE SPECIFICATION

**Consists of:**

1. Title
2. Field of the Invention
3. Prior Art
4. Drawbacks of the Prior Art
5. Object of the Invention
6. Summary of the Invention
7. Reference of the Drawing (s)
8. Detailed description of the Invention

# TERM OF A PATENT



- Twenty years from the date of filing of application for patent containing complete specification

# LEGAL RIGHTS IN PATENTS

- Patents are legal national rights granted by the state.
- Legal rights in a patent grated in one country cannot be enforced in any other country.
- For international protection a patent is required in each country. However, there are some arrangements between countries, which allow a single application to result in a number of national patents.
- Legal rights in a patent cannot be enforced automatically. Patentee has to keep a strict watch to see if any violation or infringement of his rights has been done and claim damages accordingly.

# RIGHTS OF PATENTEE (section 48)

## PRODUCT

The exclusive right to prevent third parties, without his consent, from the act of making, using, offering for sale or importing for those purposes that product in India

## PROCESS

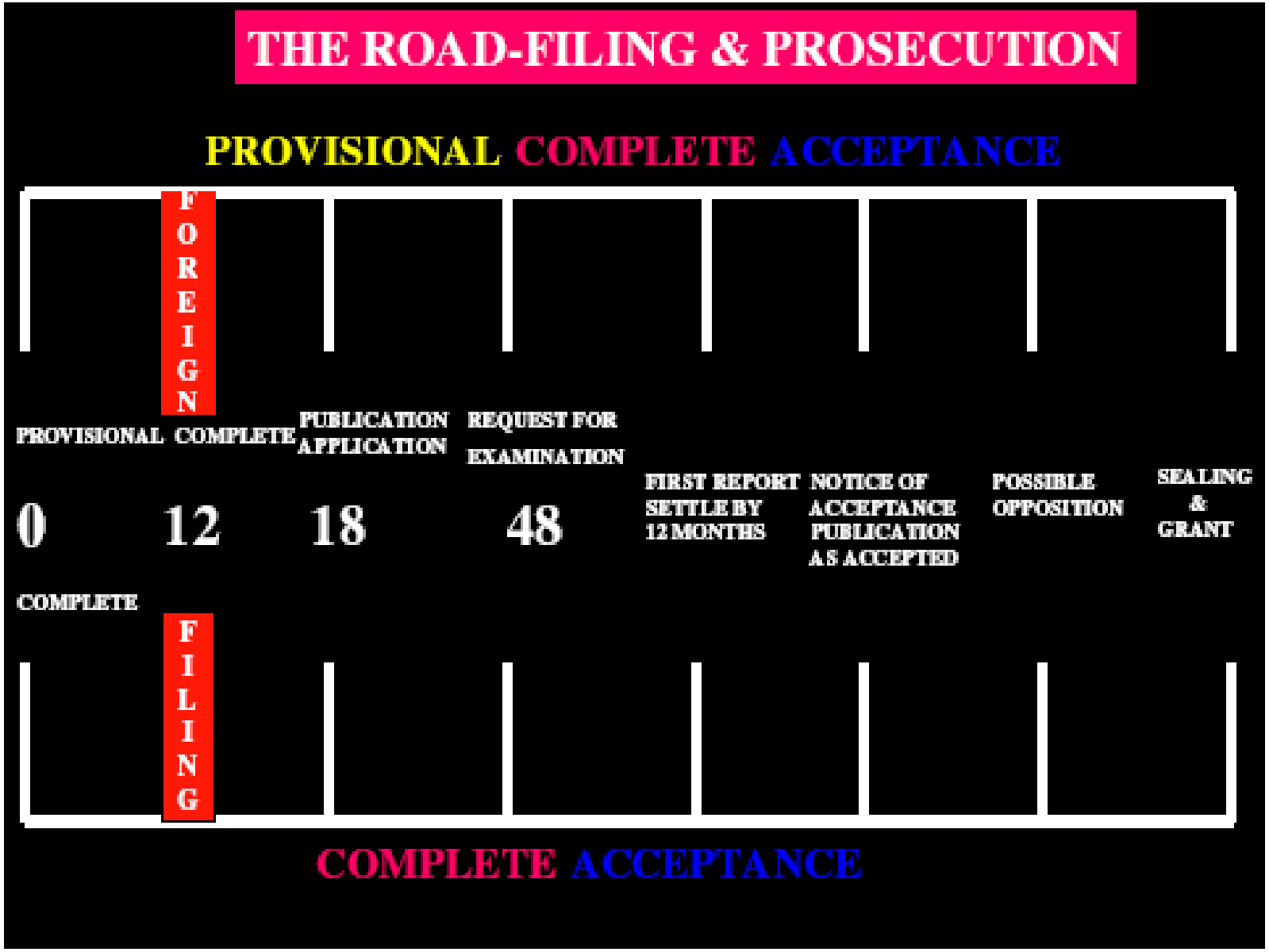
The exclusive right to prevent third parties, without his consent from the act of using that process, and for the act of using, offering for sale, selling or importing for those purposes the product obtained directly by the process in India.

# SURRENDER OF PATENT

- **SURRENDER** (under section 63)

  A patentee at any time by giving notice to the Controller, may offer to surrender his/her patent:

# PATENTING ABROAD




Source: asen2006

# PATENTING ABROAD

- **Several countries where filing is contemplated may have different patent laws and corresponding different rules (procedures)**

# PATENTING ABROAD

(a) CONVENTIONAL SYSTEM

- Filing of a national patent application in the home-country of the applicant.
- Claiming priority of the home-country application under Paris Convention
- Filing multiple foreign applications within 12 months from the date of priority
- Direct foreign filing is permissible under law for person resident in India (Section 39 of Indian Patents Acts), subject to securing in advance a Foreign permit.

# PATENTING ABROAD

- **DISADVANTAGES OF CONVENTIONAL SYSTEM**

  - **Multiple national formalities**
  - **Multiple national fees**
  - **Multiple translations**
  - **Multiple attorney – involvement**
  - **Multiple patent searches**
  - **Multiple patent examination**
  - **Multiple prosecution**

# PATENTING ABROAD

- **DISADVANTAGES OF CONVENTIONAL SYSTEM**

  - **Complex**
  - **Expensive**
  - **Only 12 months available for making decisions to enter national phase**
  - **No opportunity for reconsidering the decision to enter National phase beyond 12 months of Priority date**

# PATENTING ABROAD

## (b) REGIONAL PATENT SYSTEM

European Patent Convention (EPC)

Eurasian Patent System (EAPO)

African Regional Industrial Property Organization (ARIPO)

African Intellectual Property Organization (OAPI)

Gulf Cooperation Council (GCC)

- A regional patent granted by one Patent Office
- Rationalization/harmonisation within the regional Patent System

# PATENTING ABROAD

## (c) PATENT COOPERATION TREATY (PCT)

- An International patent filing system
- Adopted in 1970
- Operational from 1978, initially with 18 contracting states
- India joined in 1998
- Presently 137 member countries
- Open to states which are member of Paris Convention

# PATENTING ABROAD

## KEY FEATURES OF PCT

- Simplified, effective and economical system for filing patent in several countries

- Does not provide international patent

# PATENTING ABROAD

## KEY FEATURES OF PCT

- File single International patent application with national patent office (within 12 months of national filing)
- Or, directly file an international application
- Select one of the six International Search Authorities
- Pay the required fee
- Standard form and content of the application
- Same effect as a national or regional patent application

# PATENT COOPERATION TREATY
# PCT
## PCT INTERNATIONAL SEARCH REPORT

| Applicants/Agents File Ref. | | |
|---|---|---|
| Application No. | International Filing Date | Priority date |
| Applicants | | |

This International search Report is prepared by International search authority under …Article 18
This report consists of 6 sheets……
☒ It is accompanied by copy of prior art documents

1. ☐ Basis Of The Report
2. ☐ Certain Claims Were Found Not Searchable
3. ☐ Unity Of Inventuion found Lacking

4. With Regard to Title

5. With Regard to Abstract

6. With Regard to Figures

Source: asen2006

# PATENTING ABROAD

## PCT FEE

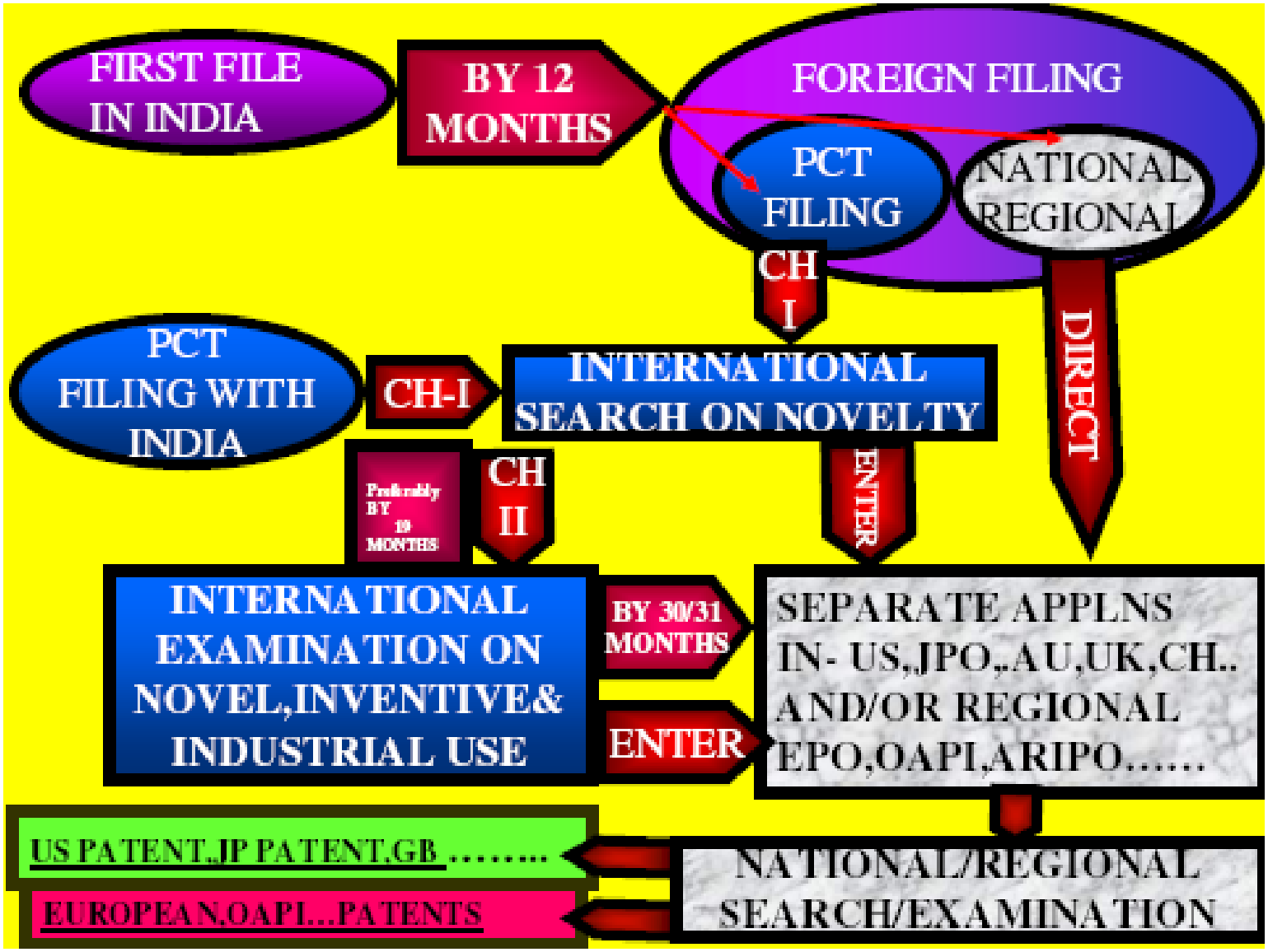
- Transmittal fee to cover work of the Receiving Office (RO)
- Search fee to cover work of International Searching Authority (ISA)
- International Fee to cover work of International Bureau (IB)

# PATENTING ABROAD

## ADVANTAGES OF PCT TO APPLICANTS

- Postpones expenditure on translation and national fee
- Keeps option open about elected offices
- Additional time available for planning patent strategy
- Opportunity to take a well considered opinion to enter national phase
- Withdrawal possible
- Reduction in national fee possible

# ROAD MAP TO PATENT FILING

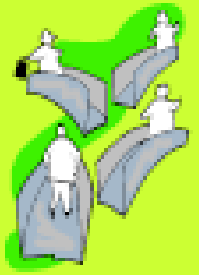



Source: asen2006

# APPLYING FOR FOREIGN PATENTS

## STRATEGIES:FACTORS UNDER CONSIDERATION

- No. OF COUNTRIES TO BE COVERED?
- WHETHER BASIC INDIAN APPLN. IS FILED?
- URGENCY IN OBTAING PATENTS AND THE COUNTRIES?
- CONFIDENCE LEVEL TO MEET PATENTABILITY CRITERIA- NOVELTY & INVENTIVE STEP?
- FINANCIAL- BUDGETARY CONSIDERATIONS.



**CHOICE OF INTERNATIONAL COVERAGE:**

* FILE INDIVIDUAL APPLICATIONS IN VARIOUS NATIONAL/REGIONAL PATENT OFFICES-USPTO,EPO,UKPTO
* FILE AN INTERNATIONAL PCT APPLICATION DESIGNATING SEVERAL COUNTRIES INCLUDING INDIA.

Source: asen2006

# CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

**At the Earth Summit held in 1992 the Convention on Biological Diversity (CBD) was concluded, to which India is a party.**

- **Conservation, sustainable use of biological diversity and equitable sharing of benefits arising from the use of biodiversity;**

- **Signatories to it to respect, preserve and maintain knowledge, innovations and practice of indigenous and local communities and encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.**

# AGREEMENT, LICENSING AND ENFORCEMENT FEATURES

# OPPOSITION [section 25 (1); 25(2)]

- Section 25 (1)

  By any person after publication but before grant (pre-grant)

- Section 25 (2)

  By any interested person before 1 year of grant notification (post-grant)

**GROUNDS**

**Wrongfully obtained**

**Prior publication/ claimed**

**Prior public knowledge or use in India**

**Lack of inventive step**

**Non-patentable invention**

**Insufficient description**

**False information relative to foreign filing**

**Incorrect mention of source of biological materials**

**Anticipation by traditional knowledge anywhere (even oral)**

# COMPULSORY LICENSE

- **Section [84, 86-90, 92-92A, 94]**

  Provided to any person only after 3 years of grant patent if

  - **Public requirement not satisfied**
  - **Not available to public in affordable price or**
  - **Not worked in India**

**Revocation [Section 85]**

**After 2 years from grant of 1st compulsory license upon application by any person or Govt on the basis of the above grounds**

# IP AGREEMENTS LICENSING

- **CONCEPT**

  IP owner **permits** third party to use the defined IP, subject to **terms** without which permission such use shall be unlawful

- No transfer of title, only permission to **use**

# IP AGREEMENTS

## ADVANTAGES OF LICENSING

### FOR LICENSOR:

- Expanded market opportunity – domestic and international
- Cuts investment costs (no need to establish subsidiary or distribution and marketing channels)
- Avoids country specific pitfalls in unfamiliar territory (local factors)-better handled by the local license
- Avoids non-use cancellation action per local laws

### FOR LICENSEE

- Availability of technology, know-how, well known brand names, and other IP assets
- Cheaper cost (in comparison to developing it self)

# IP AGREEMENTS

## LICENSING SAFEGUARDS

### RISKS:

- **Misappropriation**
- **Dilution of reputation and goodwill through misuse/wrong use**
- **Lack of adequate legal protection locally?**

### SAFEGUARDS

- **Through detailed contract governing the licensor/license relationship**

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

### MANING CLAUSE:

- Clearly identify the contracting parties

### RECITALS (important aid in interpreting the contract)

- Background of the deal
- Purpose of the agreement
- Representation of the title to the IP and authority to convey the grant

### DEFINITIONS

- IP rights (Patents, Know-how etc.) covered under the grant (SEPARATE AGREEMENTS ADVISABLE)

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## OTHER NECESSARY DEFINITIONS, e.g.

- Net sales (less taxes, discounts)
- Licensed products (made using the technology specifications and quality prescriptions)
- Affiliates
- Territory
- Effective date (date of agreement or date of all approvals, receipt, or production)
- Improvements
- Technical assistance
- Material breach

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## GRANT CLAUSE

- Manufacture/ use and sell products using the granted IP rights
- Term of the patent
- Territory
- Sole license
- Exclusive/ non-exclusive
- (exclusive license will entail higher royalties for the Licensor)
- Sub-licensing rights
- Improvement

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

- **Delivery milestones for technology and know-how transfer**
- **Technical assistance and training**

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## GUARANTEES AND WARRANTIES OF LICENSOR

- Possession/ Ownership of the IP rights
- Power and authority to enter the agreement
- Approvals, permits and consents obtained
- No known defects in t he IP rights
- No infringement of the third party
- (quality by stating to the best of knowledge and belief)
- Safety and merchantability
- Indemnity for product liability – damages and cost (Patent KH)
- No grant of More Favourable Treatment to another license (non-exclusive license)
- To convey Improvements (at no cost or terms)

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## GUARANTEES AND WARRANTIES OF LICENSEE

- Best endeavour to introduce and exploit in whole territory
- Adhere to quality control and payment stipulation
- Not to challenge or do anything which impair licensor's IP rights
- Duty to inform about improvements
- Approvals obtained

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## CONSIDERATION

- Fixed payments (Patents)
  - Upfront (non-refundable, not an advance)??
  - Annual (minimum fixed) ??
  - Milestone (on delivery of certain obligations by the Licensor, e.g. 1/3 each at the time of signing the agreement, delivery of technical documentation and commencement of commercial production
- Running royalties
  - To cease of the patent is cancelled

## PAYMENTS

- Timing
- Currency and exchange rate clause
- Subject to local taxes
- For technical training and assistance (where know-how is involved)

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## ACCOUNTING PROVISIONS

- Duty to maintain accurate records by Licensee
- Accounting procedure and standard
- Audit and inspection by Licensor or its representative
- Reports submission within 30 days of end of each quarter (or as may be agreed)
- Penalties for errors in accounting and payments

## RECORDING OF PATENT LICENCE

## LEGAL PROCEEDINGS

- Duty to infirm about infringement or misuse
- Right to bring/defend legal actions by licensee in patent

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## IMPROVEMENTS MADE BY LICENSEE

- **Rights therein**
- **Use by licensor**

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## RENEWAL OF AGREEMENT

## TERMINATION

- Without notice
- With notice (for no fault)
- Due to material breach if left uncured after notice

## CONSEQUENCE OF TERMINATION

- Restraint on future use
- Allowance for stock disposal
- Accrued rights not affected
- Confidentiality clause (if any) survive

# IP AGREEMENTS

## LICENCE CONTRACT CLAUSES

## MISCELLANEOUS

- Disclaimer of No agency relationship
- Insurance purchase to protect against product liability
- Notice prescription
- Force Majeure (Act of God, e.g. Earth quakes, floods, legislative changes, other events beyond control)
- Severability
- Entire agreement
- Modification
- Applicable law
- Dispute resolution

# IP AGREEMENTS

## CONFIDENTIALITY (NDA)

- Parties
- Recitals (background and purpose)

**E.g. Invention disclosure**

- Trade secret
- Know-how
- Other 'confidential information'

- Definition of 'Confidential Information'
  - Know-how, drawings, processes, etc.
  - Documents marked as 'confidential'
  - Oral communication reduced to writing within defined time
  - Exclusions
    - ➢ Known to recipient prior to disclosure by Discloser
    - ➢ Lawfully obtained by Recipient from the Third Party not violating the agreement with the Discloser
    - ➢ Comes into public domain without violation by recipient
    - ➢ Disclosure to Law Authorities (after notice to Discloser, so that it can take steps to seek confidential treatment of the information)

# IP AGREEMENTS

## CONFIDENTIALITY (NDA)

- **Obligations of Recipient**
- **Acknowledgement of proprietary and confidential nature and disclosers title**
- **Duty to preserve confidentiality**
  - ➢Take same degree of care as it would safeguard its own CI
  - ➢Disclosure to employees on need to know basis
  - ➢No disclosure to third parties (e.g. Consultants without prior written consent of disclosure)
  - ➢Employees and third parties to execute similar NDA
- **Duty to use only for purpose for which CI is received**
- **Duty to return on expiration of the agreement**
- **Duty not to misuse for file for registration on its own name**
- **Duty to not to assign without prior consent of the Disclose (which may not be unreasonably withheld)**
- **Duty to notify the Discloser, if improper law/ breach occurs**

# IP AGREEMENTS

## CONFIDENTIALITY (NDA)

- **Disclosure not be construed as a Grant or License even by implication**
- **Finality- Supersedes all prior understanding agreements**
- **Binding on Successors of Recipient**
- **Governing law**
- **Disputes resolution (method, remedies and jurisdiction)**
- **Obligations above mentioned of the Recipient to SURVIVE the term (either for a fixed period or undefined period)**

# IP AGREEMENTS

## NATURE OF CLAIMS (OPPOSITION)

- **Patent Office**
- **GROUNDS**
  - Obvious (no inventive step)
  - Published in India or elsewhere in any document before the priority date of the claim
  - Publicly known/ used in India before the priority of the claim
  - Not an invention
  - Does not sufficiently or clearly described the invention or the method
  - Materially false information furnished
  - Wrongly mentions the source or geographical origin of biological material used in the invention
  - Anticipated since knowledge available with local or indigenous community in India or elsewhere (documentation or otherwise)
- **TIME**
  - Pre-grant or within one year of the grant

# NATURE OF CLAIMS

## CANCELLATION

- **Patent Office**
- **GROUNDS same as in OPPOSITION**

# NATURE OF CLAIMS

## SUIT FOR INFRINGEMENT

### Cause of action arises when

Patents, (e.g. identical patented process leading to identical product)

- Trademark
- A statutory remedy for registered mark
- Mere proof of registration is sufficient
- Not necessary to prove reputation and goodwill
- Similar goods/services on proof of likely public CONFUSION
- Dissimilar goods/services on proof of REPUTATION and detrimental effect on the mark
- Use as part of corporate name in respect of same goods

### Passing Off

- Remedy under common law : the plaintiff's mark's need not be registered for the goods in question
- Necessary to prove:
  - **reputation of the plaintiff in the mark**
  - **misrepresentation**
  - **damage / harm**

# ENFORCEMENT

**NATURE OF CLAIMS**
(Breach of Contract)

E.g. License Agreement
Non-Disclosure Agreement (NDA)

# ENFORCEMENT

## COURT SYSTEM

**HIERARCHY**

- District court
- High court
- Supreme court

**IPR DISPUTES TO BE LODGED IN DISTRICT COURT**

Exception:

- High court has original jurisdiction and
- Damages sought exceeds the minimum pecuniary jurisdiction of the High court

**JURISDICTION** –

- General rule : S.20 CPC - where the Defendant resides or carries on business or the cause of action arises in whole or in part.
- Exception for TM infringement and copyright cases – where

# ENFORCEMENT

## PROCEDURE

**Rules prescribed by IP laws, code of civil procedure and the court rules regarding**

- **Time limits for institution of suits (3 years) and appeals (30-90 days) - delay can defeat action**
- **Form of Pleadings**
- **Time limits for taking each step in completion of pleadings**
- **Notice/Service of papers on the other side**
- **Framing of issues Enforcement**

# ENFORCEMENT

## PROCEDURE

**Evidence (to be lead in regard to contested points)**

- Documentary
- Oral
- Real - such as models, machines, products, etc.

**Presentation of evidence**

- By affidavit (must cover only facts; no submissions)
- Cross examination of the witness who filed the affidavit
- Market survey evidence - shows the “public mind”
- Expert evidence

**Hearing**

**Decision**

# ENFORCEMENT

## REMEDIES

**CIVIL (Injunctions, damages etc)**

**CRIMINAL (Imprisonment)**

**ADMINISTRATIVE (Customs)**

# ENFORCEMENT

## CIVIL REMEDIES

### PRELIMINARY/INTERIM INJUNCTION

ex-parte or after notice

Three ingredients

- prima-facie case
- irreparable injury
- balance of convenience

Anton Piller orders (to preserve evidence the court orders entry by solicitors into the Defendant premises and taking into safe custody the evidence. Also the Defendant required to disclose names and addresses of suppliers and customers. In India, in addition, the courts grant lock braking power and availing police assistance if required)

John-Doe orders (court appointed Commissioners to enter premises of ANY suspected party to collect evidence of infringement, e.g. ICC/Cable Operators

Norwich Pharmacal orders (third parties also required to disclose information)

Mareva injunction (restrains the Defendant from removing assets or dealing with them in any way, so as to frustrate a potential monitory judgment)

### PERMANENT INJUNCTION ON MERITS AFTER FULL HEARING

### DAMAGES OR RENDITION OF ACCOUNTS

### COSTS

# ENFORCEMENT

## CRIMINAL REMEDIES

### CRIMINAL REMEDIES IN CERTAIN CASES UNDER LAW OF

**TRADEMARKS (Falsification, false application of trademark, false claim of ® symbol)**
**Punishment – seizure, imprisonment (6 months to 3-years) and fine (Rs.50,000/- to Rs. 2 lacs)**
**Prerequisite - Registrar's opinion**

**COPYRIGHT (pirated copies)**
**Punishment seizure, imprisonment (6 months to 3-years) and fine (Rs.50,000/- to Rs. 2 lacs)**
**Software – (7 days up to 3-years of imprisonment) and above prescribed fine**

**DESIGN LAW - no similar remedy – maximum damages fixed at Rs.50,000/-**

# QUICK OVERVIEW OF COURT SYSTEM IN IPR CONTEXT

- **OVERBURDENED: therefore slow and unsuitable for full and final settlement of IPR disputes – cases do not reach trial Typically**

- **Lack of special knowledge or non appreciation of the**
- **gravity of IP related offenses (nominal damages)**

- **High cost of litigation**

- **Some High Courts have been very active and have been in forefront of law making**
  - **Injunction and special interim reliefs**
  - **Protection for well known marks**

# SO IS THERE AN ALTERNATIVE

## ALTERNATIVE DISPUTE RESOLUTION

**Two methods -Mediation and Arbitration**

**ADR** **- an alternate to litigation (adversarial in character)**
**- Gradual success elsewhere**

# MEDIATION

- Voluntary submission of dispute (by a contract or otherwise)

- Neutral mediator

- Objective to ASSIST the parties in reaching amicable settlement (settles the matter on the basis of the respective interests of the parties rather than on legal basis alone).
- No power to impose

- Settlement if reached has the effect of being a contract between the parties

- Voluntary character: both submission as well as termination at any stage

  Advantages:

  Non-Adversarial

  informal and not bound by strict rules of legal procedure

# ARBITRATION

**VOLUNTARY SUBMISSION**

**HAS THE ABOVE FEATURES AS IN MEDIATION.**

- **more formal than mediation**
- **less formal than litigation in terms of procedures**

**FLEXIBILITY: Parties to decide**

- **the rules of procedures with reference to an Arbitral Institution**
- **the powers conferred on the Arbitrator**
- **The applicable law and**
- **The venue**

# OTHER ADVANTAGES OF ADR (ARBITRATION)

- **Speedy disposal**
- **Award is final and binding - absence of institutional appeal**
- **Easy enforceability**
- **Expert determination possible**
- **Confidentiality of arbitration**
- **Confidentiality of know-how and other confidential information duly preserved**
- **Other**

# IPR ISSUES RELATED TO BIOTECHNOLOGY

# WHAT SHOULD BE PROTECTED

- **Article 27(3)(b) of TRIPS excludes**

  "…..Plants and animals other than micro-organism, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes and plant varieties….."

- **TRIPS dictates the law:**

  - New plant varieties have to be protected by an effective "***sui-generis***" system or by patents or a combination thereof.

  - Plant varieties produced by traditional methods of breeding and screening techniques of mutation, cross-fertilization, recombinant techniques will become subject matter of Protection of *sui-generis* system.

# TRIPS & INDIAN LAWS

| Phase I | Phase II | Phase III |
|---|---|---|
| • Patent (Am.) Act,99<br>• Pipeline protection for medicines, drugs, agro-chem (WTO application)<br>• examination & grant after 2005 | • Patent (Am.) Act,02<br>• TRIPS definition for “invention”<br>• Chemical process includes “biotech, microbiological & biochemical processes”<br>• Uniform term: 20<br>• WTO provision to continue | 2005:<br>• All inventions to be patentable<br>• product + process patents<br>• fully TRIPS-compliant |

# UTILITY ASPECTS

- **Specific**
- **Credible**
- **Substantial**

# BIOTECHNOLOGY- INNOVATIONS

**1873 –** Louis Pasteur, Yeast, free from organic germs

**1980 -** Microorg. Diamond vs. Chakrabarty

**1985 –** GM maize Tryptophan – rejected

Board of appeals, finally allowed

**1987 –** Oyster (triploid) not patentable due to obviousness but was clear that living organisms can be patented but not patents for human beings

# BIOTECHNOLOGY- INNOVATIONS

- Recombinant DNA
- PCR technology
- Sequencing and analysis
- Microarray/ Functional genomics
- Transgenics
- Bioinformatics

# BIOTECHNOLOGICAL PATENTS

- **Process/methods** - Inventions on the making of fermented food products
- **Products** - Isolated organisms
  - Plant extract containing a specific indication about its utility
  - Fermented food and beverages
  - Chemical substance derived from extraction or isolation such as Vitamin B 12

# BIOTECHNOLOGICAL PATENTS

- **Composition** - Vaccine composition
- **New users** - Bioremediation based on enzymes
- **Use of Microorganisms** - Cultivated bacteria and fermentation of similar cultivation

  - Uses of microorganisms containing halogens to dissolve hydrocarbon

# MICRO-ORGANISM

- India is rich in genetic diversity
- Legislative framework / Regular mechanism for protection
- Deposit patentable living organism with a recognized Institution (Budapest Treaty)
- Many Institutions exist
- Can act as International depository authority

# INTERNATIONAL DEPOSITORY AUTHORITIES UNDER BUDAPEST TREATY

Microbial Type Collection and Gene Bank,

Institute of Microbial Technology, Chandigarh, India

(Bacteria, Yeast, Fungi, Actiomycetes, Plasmids)

# MICROBIOLOGICAL INVENTIONS

- **Process**

***Methods*** – Novel methods of cloning

Methods of producing cholera vaccine

Typhoid vaccine, human insulin

Blood clotting factors, Bt proteins

***Uses*** Use of combined microorganisms to degrade oil; Use of microorganisms for making L-Lysine.

# MICROBIOLOGICAL INVENTIONS

- **Product**

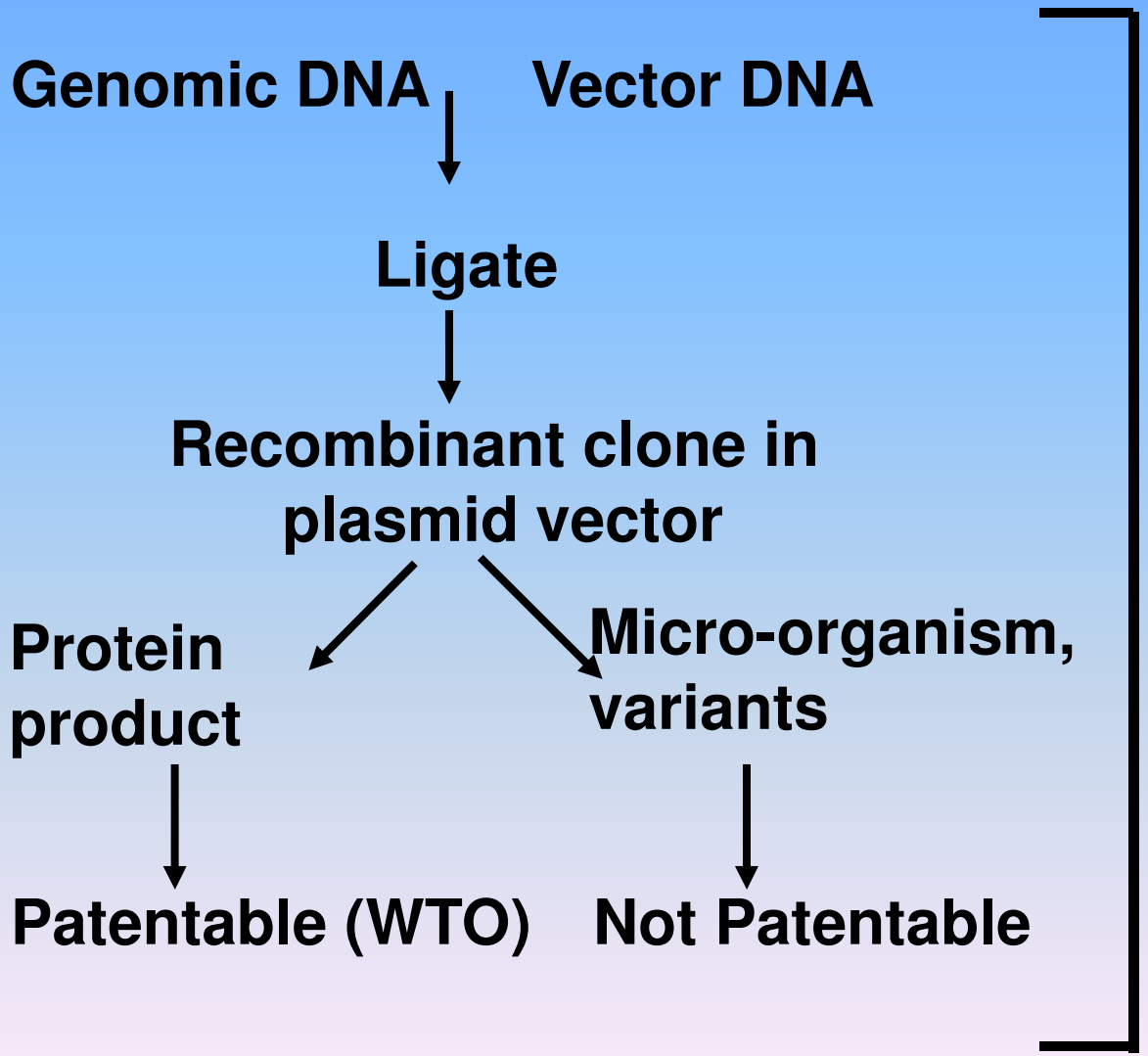
***Biosynthetic products*** – Bt protein, *Taq* polymerase,Clotting factor, Hepatitis A vaccine

***Organisms*** *T. aquaticus*

Hepatitis A strain

***Composition*** Vaccine composition

# TYPICAL MICROBIAL INVENTION




**Process - yes**

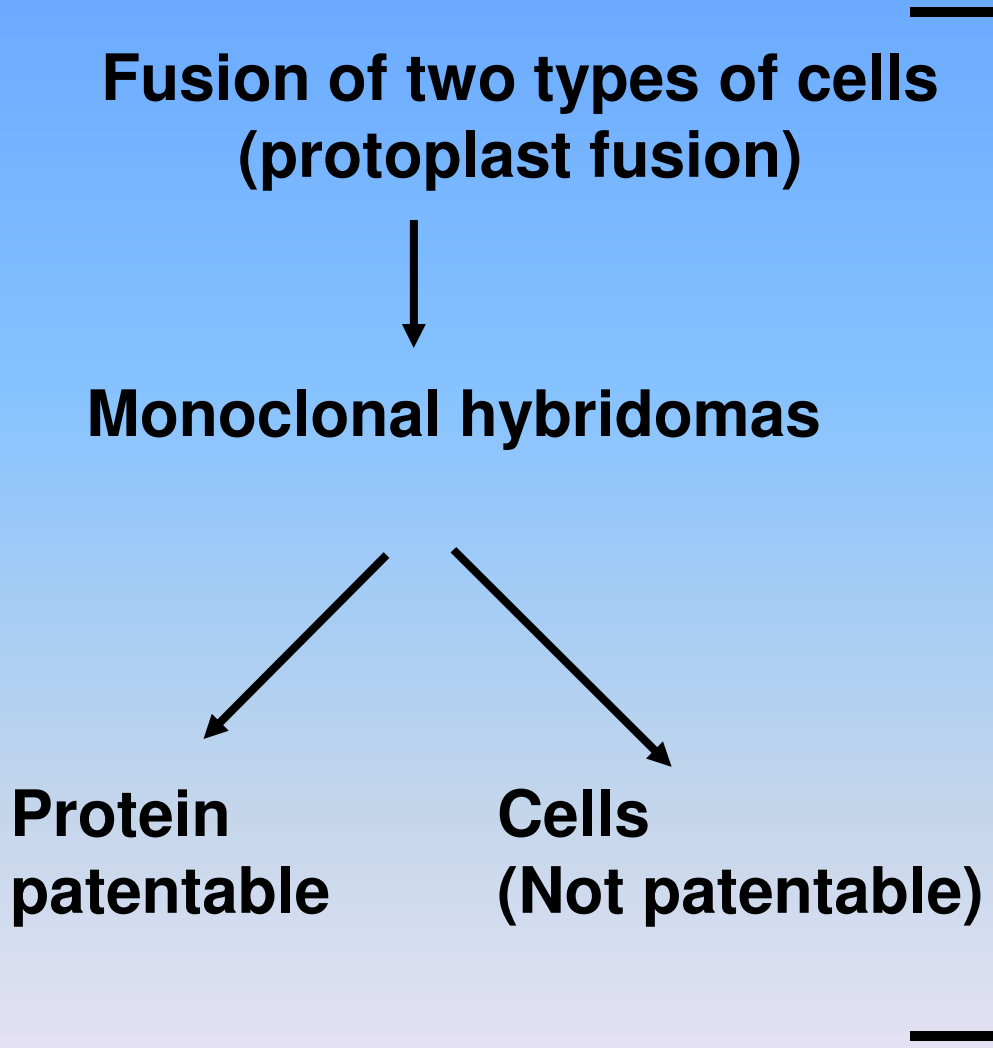
**Product – WTO Appl**

- Human insulin
- Immunoglobin
- Vaccine
- Blood clotting factor
- Bt toxin

# MICROBIAL AND ENZYME PATENTS

- **Composition** - Vaccine composition
- **New users** - Bioremediation based on enzymes
- **Use of Microorganisms**- Cultivated bacteria and fermentation of similar cultivation
  - Uses of microorganisms containing halogens to dissolve hydrocarbon

# HYBRIDOMA TECHNOLOGY




**Process is patentable**

- Blood group
- Hepatitis B
- HCG
- HIV
- Polio
- Malaria

**Product is not patentable**

# CHOLERA VACCINE

- **Vaccine** per se: hit by 5(a)

  "Invention where only methods or processes are patentable: claiming substances intended for use, or capable of being used as food, or medicine or drug……"

- **Process** for producing the vaccine

  - patentable

  -IP 182323 obtained

# *BACILLUS THURINGIENSIS*

- **Methods & compositions for detection of bacterial endotoxins**
- **Kits for detection of endotoxins**
- **Stains-higher yields of endotoxins**
- **Mutations at 2 different AA positions**
- **Hybrid Bt-novel broad spectrum**
- **Various strains of Bt (mutants)**

# DNA AMPLIFICATION

- PCR used for amplification of genes

- Taq Polymerase
  - -Cetus Corp
  - - Hoffman La-Roche
  - - Promega corp

- Screening of transformants by PCR

# CASE STUDY

- ***Taq* polymerase**
  - A naturally occurring enzyme from *T. aquaticus* that has applications in a procedure call PCR
  - **Patents claimed:**
    - the purification of Taq polymerase from *T. aquaticus*
    - the PCR process
    - a recombinant form of Taq polymerase

# TAQ POLYMERASE

- The process of purifying this enzyme was patentable because it required some ingenuity to purify the enzyme from bacteria in which it lived
  - Such a process may no longer be granted because protein purification methods are more common, thus failing the requirement for "unobviousness".

# TAQ POLYMERASE

- The patent on recombinant form of *Taq* polymerase is an example of the type of patent which raises the most controversy

# PRODUCT VS. PROCESS VS. USE CLAIMS

- **Product: US5589581, "DNA sequences useful for the synthesis of carotenoids", claims stipulate isolated and purified DNAs which encode enzymes involved in the biosynthesis of several carotenoids.**

- **Process: EPO604662, "Method of transforming monocotyledon", claim stipulate methods, and details thereof, for *agrobacterium*-mediated transformation of monocotyledons (including rice).**

- **Product/Process: W09113078, "enhanced regeneration system", claims stipulate both the methods for the regeneration of cereals plants, as well as the transgenic.**

# METHODS OF MEDICAL TREATMENT APPLIED TO HUMANS & ANIMALS

- Excluded from patentability
- Many cases in developed countries have worked around such ban

o ICI / Cleaning Plaque

  - Use of the compositions as sole oral hygiene agent for plaque cleaning for cosmetic effect and not medical treatment
  - EPO rejected the argument as ICI's claim also defines a treatment of the human body.
  - Not patentable

# THERAPEUTIC RELATED INVENTIONS

- Methods of medical treatment not patentable but products or composition are patentable
- Inventions in the form of products or Substance
  - New products, new compounds
  - New medical use of known compound
  - Second and further medical use of a known compound ("**Swiss Form**" Claims)

# INDIAN PATENT LAW - RECENT DEVELOPMENTS

## Impact of Dimminaco

- Landmark judgment
- In consonance with world patent practice
- Most processes in the biotechnology field will be patentable: irrespective of whether resultant product is living or non-living

# PATENTING OF DNA

# CRITERIA FOR GENE PATENTING

- **Subject matter**

  Isolated gene is a composition of matter

- **Novelty**

  Each gene is new only once

- **Utility**

  How the gene is synthesized and scaled up

- **Non-obviousness**

  Prior art seldom teaches (who undue experimentation) what the next unique gene will be

  Unless patent is based on gene isolation technique

# WHY PATENT GENES?

- To award inventors for their innovations.
- Business advantage
  - More than 500,000 patents have been applied for on genes or genes sequences worldwide.

# MULTIPLE PATENTS

- A single long DNA sequence can give rise to many different, independent patents
  - ESTs
  - Entire gene
  - Different SNPs
  - Overlapping DNA sequences

# APPLICATION OF DNA SEQUENCES IN RELATION TO PATENT CLAIMS

- Diagnostic testing
- Research tools
- Gene therapy
- Production of Proteins

BRCA1

CCR5 Receptor

Cystic fibrosis

Human insulin

# UTILITY OF BIOTECHNOLOGICAL INVENTIONS

- **Specific utility** — Gene probe, chromosome marker not specific
- **Substantial utility** — Therapeutic method of treatment or method of identifying compounds are Substantial
  Transgenic mice as snake food not substantial utility
- **Credible utility** — Perpetual motion machine not credible

**Well-establish utility of invention is always acceptable and easily recognized**

# GENE PATENT

- Human genes can be patentable if they can be distinguished from genes as they naturally occur in human bodies – naturally occurring genes cannot be patented
- Not patentable in India

# GENE PATENT

- First gene patent was for cystic fibrosis gene (US 5,776,677)
- Claims
  - ❖ method of screening a patient
  - ❖ kits for these assays
  - ❖ no gene claims

**However related applications exist which cover the gene *per se***

# GENE PATENT - BRCA

- Two breast cancer genes patented in US
- BRCA1 & BRCA2
- Several- in part applications pending
- Claims: normal BRCA1 gene and altered mutation at one of four specified positions
- Kit for detecting mutations
- Production of polypeptide
- Primers for PCR

# GENE PATENT – BRCA2

- Claims for normal and mutated gene
- 39 specifically defined mutations
- Cloning and expression
- Methods of producing BRCA2 polypeptides
- Primers for PCR amplification
- US 6,033,857 for diagnosing predisposition to breast cancer, wide range of methodologies

# PROCESS VS. PRODUCT

- Patents may be issued over DNA sequences, on ways of making DNA sequences, or on ways of using DNA sequences
- A patent on DNA sequence itself prevents all others from making, using, selling, or importing that DNA sequences for any purpose

# APPLICATION OF PATENTS TO DNA SEQUENCES

- As long as form in which DNA sequences is claimed would not exist in nature without human intervention, sequence may be subject of a patent claim

**Examples**

- DNA sequence in isolated form
- DNA sequence together with another sequence
- DNA sequence that does not exist in nature even if close to it

# WHAT IS SPECIAL ABOUT DNA SEQUENCES

- DNA sequences are different because they blur the line between particular object (DNA molecule) and information (the DNA sequence of a particular individual)

- Patent law aims at avoiding patents on information

  Exclusion of scientific principles and abstract theorems

# INVENTIONS AGAINST PUBLIC ORDER AND MORALITY VALUES

# STEMS CELLS

**Researching and patenting human stem cells-related technology: a problem of morality (disposing of the embryos) and os legality (patentable inventions v. non- patentable discoveries)**

# HARVARD ONCOMOUSE

- Genetically engineered mouse
- Super susceptible to cancer
- Inserted myc oncogene (mam. Sp. Pro.) into new embryo of normal mouse
- Claims for the mouse (product + process)
- 1984 – filed application
- 1988 – US patent granted

# HARVARD ONCOMOUSE

- US 4,736,866 Philip Leder and Timothy A Stewart

- A transgenic non-human mammal all of whose germ cells and somatic cells contain recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage

- Cover all mammal and the projene of the animals

# HARVARD ONCOMOUSE

- E.U prohibits
- Art 53 (a) public order of morality
- Art 53 (b) plants or animals (except microbe)
- EPO – oncomouse new variety of animal so ineligible
- Appealed
- Sent back to examiners (1990) to reexamine under Art 53 (a)
- Patent granted
- In Abeyance

# HARVARD ONCOMOUSE

- Canada
- Debate in several countries over ethical issues
- Denied by commissioner and Federal Trail court
- FCA  allows in August 2000
- Supreme court is yet to decide

# FAQ'S ABOUT PATENTS AND PATENTING

# FAQ'S-PATENTS

- ***Can the legal rights in a patent granted in one country be enforced in any other country or countries?***

  No, the legal rights in a patent can be enforced only within the territorial limits of the country which grants its. For example, the legal rights in patents granted in India can be enforced only in India. Similarly, the legal rights in the patents granted in USA can be enforced only in USA, and so on.

- ***Is there anything called "World Patent"***

  There is nothing like "World Patent" of "International Patent". A patent granted by a country is valid, and the legal rights can be enforced, only within the jurisdiction of that country. In other words, for securing legal rights by patents in many countries, separate applications have to be filed in each of the desired countries according to the law and procedure of that country concerned.

# FAQ'S- PATENTS

- ***Who is a "Patentee"?***

  A Patentee is the applicant for a patent for the time being entered in the Register of Patents maintained in the Patent Office and is the grantee or proprietor of the invention disclosed in the said patent

- ***Can the legal rights in a patent be enforced automatically?***

  No, for enforcing the legal rights in a patent, the patentee should keep a strict watch to ascertain whether someone is infringing his rights in the patent without his permission and decide the appropriate legal action to be taken to stop such infringement and claim damages.

- ***Does the Government granting the patent give financial or any other award or assistance to the inventor/ patentee in granting the patent.***

  The Government (State) does not give financial or any other award or assistance to the inventor/ patentee in granting the patent.

# FAQ'S - PATENTS

- ***What do patents do?***

  The give patentees (proprietors) the right to take legal action to prevent other people from exploiting a patented invention without the proprietor's permission. A person who develops an invention does not need a patent for commercializing it. He already has the right to commercialize if it is not already protected by a patent by someone else. But in the event of the invention not being patented he does not have the legal rights to stop others from working the said invention

- ***What don't patents do?***

  The grant of a patent for an invention does not guarantee the merit or any other commercial value of the invention disclosed. The State (country) which grants the patent does not also guarantee the validity of the patent granted.

# FAQ'S PATENTABLE INVENTIONS

- ***What categories of inventions are patentable?***

  The inventions which are patentable in a country are specified in the patent legislation of that country. In India Patents Act 1970 (Amnd 2005), which governs the grant of patents, lays down the conditions for an invention to be patentable. For securing a patent under the Act the invention must be i. new and useful ii. involving an inventive step iii. Capable of industrial application

- ***How is novelty of an invention determined?***

  The novelty of an invention id judged by taking into consideration the knowledge available anywhere in the world in the relevant filed at the time of filing the application for patent. In other words, the invention should not be publicly known anywhere in the world prior to the filing of the application for a patent. It is to be noted that the disclosure of the invention to the public by the inventor himself, before the filing of the application for a patent, by publication or exhibiting, would prejudice the novelty of the invention and would stand in the way of subsequent patenting of the said invention

# FAQ'S PATENTABLE INVENTIONS

- ***What is meant by "inventive step"?***

  An invention is considered to have an inventive step if, when compared to what is already known, the invention would not be obvious to someone with reasonable knowledge and experience in the subject

- ***What is meant by "industrial application"?***

  The expression "industrial application" means that the invention must take a practical form such as apparatus, device or a product such as a new material, compound, substance or an industrial process producing the said product. Any improvement of the above is also included in this category.

# FAQ'S PATENTABLE INVENTIONS

- ***Are all inventions satisfying the above criteria patentable?***

  No, certain categories of inventions which satisfy all criteria of patentability may still not be patentable. Such categories of inventions are specified in the patent legislation of the country concerned. In India, Sections 3 and 4 of the Patents Act 1970, specify the categories of inventions which are not patentable. Such inventions include among others, abstracts, principle, discovery, new use of a known substance, simple admixtures, treatment of human beings, animals and plants and inventions relating to atomic energy. In addition, accordingly to Section 5 of the Act, in certain categories of inventions only process protection is possible. Some examples of inventions which are patentable are given below. Processes for the production of new compounds, improvements of existing processes for the production of known compounds/ composition(s), development of new machines, devices or an improved machine/device and synergistic compositions (except those which fall under the category of food/drug).

# FAQ'S FILING OF APPLICATIONS

- ***Who can apply for a patent??***

  An application for a patent may be made by any person, whether a citizen of India or not, claiming to be the true and first inventor of the invention or his assignee or the legal representative of a deceased person who immediately before his death was entitled to make the application. The application may also be filed by any of the above persons jointly with any other person. The term "person" includes the Government. In the case of inventions originating from the constituent laboratories of CSIR, the application has to be filed in the name of the CISR only and not in the name of individual laboratory.

- ***Can a company or a firm be named as the true and first inventor?***

  A company or a firm cannot be names as a true and first inventor. The inventor should be a natural person. A firm or a company can be an applicant for the patent by virtue of an assignment of the invention by the true and first inventor. Accordingly CSIR or one of its constituent laboratories cannot be true and first inventor. The first and true inventor should be a person who was assigned the R&D work. Such a person assigns all the rights in the invention disclosed in the application to CSIR as per the terms and conditions of his/her appointment in the CSIR.

# FAQ'S FILING OF APPLICATIONS

- ***What are criteria for naming inventor?***

  The person who has contributed intellectually for achieving the results should be named as the inventor. This should be done irrespective of the position or qualification the person possesses. The order of mentioning the inventors (if more than one) in the application is not important. It can be in any order since all of them are considered to have equally contributed intellectually towards the development of the invention. To avoid any difficulties in deciding the names of the true and first inventor(s) in the application it is very essential to maintain proper records of day-to-day work done by the members of the project. This record may be in the form of a diary. The maintenance of such a diary not only helps in identifying the persons(s) who has (have) contributed intellectually towards the development of the invention but also establishes the date of conception of the invention which will help in establishing the ownership of the invention in any dispute arises at a later date.

# FAQ'S FILING OF APPLICATIONS

- ***When should an application for a patent be filed?***

  An application for a patent should be filed at the earliest possible time after developing the invention at the laboratory level. The filing should not be delayed till the complete development of the know-how or making the invention commercially viable.

- ***Should the filing of an application for a patent be deferred till the invention is scaled up or made commercially viable?***

  If the filing is delayed there is a danger of the invention losing its novelty by the disclosure of the invention to the public. Therefore, the application for a patent should be filed immediately on the successful development of the invention at laboratory level.

# FAQ'S FILING OF APPLICATIONS

- ***Is it possible to publish the invention as well as obtain a patent therefor?***

  Since the novelty of the invention will be lost by the publication of the invention (even by the inventor himself) the application for a patent should be filed before the publication. The invention can be published after filing the application disclosing all the essential features of the invention (complete specification). In the publication, the number of application for patent may be given by way of notice to the public. If the essential features of the invention are not given in the application there is a danger in publishing the invention after filing such an application. Therefore, care should be taken to draft the document disclosing the essential features of the invention diligently. It is to be noted that if the invention covered in an application for a patent has also be protected in foreign countries, then the said technology must not be transferred for commercialization immediately after filing the application in India; the transfer should be deferred till all the applications in the desired countries are filed. It is advisable not to publish the invention till the application for a patent disclosing the essential details of the inventions are filed.

# COMMERCIALISATION OF INVENTION

- ***Can an invention be commercialized without obtaining a patent therefor?***

  Yes, provided no one else already has the legal rights to such an invention in the country concerned. Such a commercialization will prevent anyone else from subsequently getting a patent for the said invention, but would not prevent them from copying the invention. In other words, if not patent is granted for an invention in India, or the life of a patents has expired, or the patent has lapsed due to non-payment of the renewal fees, the said invention can be commercially used in India by anyone without the permission of the patentee.

- ***Is it necessary to defer commercialization of an invention till a patent is secured for the invention?***

  The procedure for the grant of a patent is quite length. Therefore, the commercialization of an invention covered in a patent application need not be deferred till a patent is granted on the said application. In case an application for patent has been filed for an invention and it has to be commercialized immediately before the grant of a patent on the said application, it can be done. The only precaution to be taken is to execute an appropriate secrecy agreement with the prospective client in an appropriate manner to safeguard the interest in the application.

# COMMERCIALISATION OF INVENTION

- ***Can a technology covered in an application for a patent be transferred immediately after filing the application for a patent?***

The technology (know-how) in respect of the invention covered in an application for a patent can be transferred immediately after filing the application for a patent disclosing the essential details of the invention. In that case, it is essential to execute an appropriate secrecy agreement with the party to whom the technology is to be transferred safeguarding the interest in the pending application for patent.

# DOCUMENTS REQUIRED FOR FILING

- ***What are documents required for filing an application for a patent in India?***

  The documents required are i. The appropriate application from ii. The documents called specification disclosing the invention, iii. Drawing, if any, in support of the invention disclosed, iv. The prescribed fees.

- ***What is meant by a patent specification?***

  The grant of a patent for an invention is based on the disclosure of the scientific and technical details of the invention proposed to be protected. These details are contained in a document called ‘specification’. The patent specification may be either provisional or a complete specification.

# DOCUMENTS REQUIRED FOR FILING

- ***What is a provisional specification?***

  The provisional specification discloses only the essence or the nature of the invention. It does not disclose the essential features of the invention to be protected. It does not also contain the statement of claims defining the scope of legal protection to be secured. Therefore, the filing of the application accompanied with a provisional specification does not confer any legal rights on the applicant.

- ***What is a complete specification?***

  The complete specification discloses the full details of the invention to be protected. It not only contains the nature of the invention but also the best mode of carrying out the invention disclosed. It also contains the important part, namely the statement of claims, which defines the scope of the legal protection being sought for. The date of the patent is the date of filing the complete specification and legal rights accrues to the applicant on the grant of a patent thereon from the date of filing the complete specifications

# DOCUMENTS REQUIRED FOR FILING

- ***Should an application for a patent be filed always accompanied with a provisional specification?***

  It is not necessary to file the application for a patent always accompanied with a provisional specification. The application can be filed accompanied with complete specification directly. The application for patent accompanied with a provisional specification may be filed in the t he vent some more work has to be completed in the laboratory regarding the invention and/or there may be a delay in drafting the complete specification defining the full scope of the protection desired. In such circumstances, the filing of the application accompanied with a provisional specification will help registering the priority of the invention and also safeguarding the novelty of the invention. The filling of the application accompanied with the provisional specification serves the important purpose of recording the priority of the invention at the Patent Office on a first-come-first-served basis.

# DOCUMENTS REQUIRED FOR FILING

- ***Is its necessary to file the complete specification after filing the application accompanied with a provisional specification?***

  Yes, the complete specification has to be filed in respect of all the applications filed accompanied with a provisional specification. The complete specification should be filed in such cases within 12 month from the date of filing the application accompanied with a provisional specification. A further (maximum) extension of three months beyond the above said period can be secured. If the complete specification is not filed within t he above said period, the application filed accompanied with a provisional specification will be treated by the Controller of Patents as abandoned and no further action can be taken on the said said application. The Controller of Patents takes up the applications for examination only after the complete specification is filed.

# DOCUMENTS REQUIRED FOR FILING

- ***Will the contents of the application, so abandoned due to non-filing of the complete specification after filing the provisional specification, be open to the public?***

  The Controller of Patents will keep the information disclosed in such abandoned applications confidential forever. In other words, he will not make the information available to the public. Then a fresh application can be filed accompanied by a provisional specification for the same invention provided the invention has not been made public in the meantime by the applicant/inventor or anybody else.

- ***Will the provisional specification filed be cancelled after filing the complete specification?***

  No, the provisional specification is not a rough draft of the compete specification. The complete specification, therefore does not replace the provisional specification. Both the specifications are independent documents and will be maintained by the Controller of Patents. The provisional specification will be useful to determine the priority date of the invention in case any dispute arises at a later date.

# DOCUMENTS REQUIRED FOR FILING

- ***What is meant by Statement of Claims?***

The statement of claims contained in the complete specification defines the scope of protection sought for. It defines clearly the invention disclosed in the specification. There can be more than one claim. The first claim is the principal claim, which defines the essential novel features of the invention. The features, which are optional, are included in the subordinate (subsequent) claims. The claims should define clearly the process/ device/ apparatus/ composition and not their advantages and/or functions/ properties. The following types of claims are not allowed as they do not define any inventions:

I. I claim to be the inventor of the invention disclosed in the specification

II. I claim that the invention disclosed in the specification is new and has not been used before.

III. I claim the advantages of the invention disclosed in the specification.

# DOCUMENTS REQUIRED FOR FILING

- ***How much time does it take to obtain a patent in India?***

  The procedure for obtaining a patent is a very lengthy one. As the situation stands now, on an average, it takes about five years to secure a patent in India. It should be noted that the grant of a patent takes retrospective effect, i.e. from the date of filing the complete specification, which is the date of the patent. The know-how of the invention being developed may ordinarily take four to five years. In such case, it is possible that the time one develops the know-how of the invention and is in a position to transfer the technology covered in the application for a patent, the patent also would be ready for grant. In other words, the long time taken for the grant of a patent will not be disadvantage if the application if filed at the early stage of the development of the invention at the laboratory level.

# OTHER INFORMATION

- ***What is meant by "term of a patent"?***

  The expression "term of a patent" means the period for which the exclusive right in the invention covered in a patent can be exercised by the patentee. This period various from country to country. In India the period in respect of patents relating to inventions in the areas of drugs, medicines and food is 5 years from the date of sealing (grant) or seven years from eh date of the patent whichever period is shorter and 14 years from the date of the patent in respect of all other inventions.

- ***What should be done to maintain a patent?***

  In order to keep a patent in force the prescribed annual renewal fees should be paid within t he prescribed time. If the renewal fees are not paid the patent will lapse and the invention disclosed therein will become public property.

# OTHER INFORMATION

- ***Can a lapsed patent or a patent whose term has expired be registered again?***

  No, this is because by the first grant of a patent for that invention its novelty is lost.

- ***Can a lapsed patent be restored?***

  If a patent has lapsed due to the non-payment of the renewal fees, it can be restored on making an application in the prescribed manner to the Controller of Patents. Such an application should be made within one year from the date of lapsing of the patent. If such an application is made within the time and the non-payment of the renewal fees is unintentional and there has been no undue delay, the Controller may, if there is no opposition for the restoration, restore the patent as per the term and conditions which he considers fit.

- ***Does the use of the information contained in the patent documents for R & D purposes constitute infringement?***

  The use of the information contained in the patent documents for R&D and for imparting education, without the permission of the patentee does not constitute infringement of the patent. In other words, the information can be freely used for the above mentioned purposes.

# PATENTS TOP 10

1. **There is NO such thing as an international patent.**

   There are “international applications” called PCT applications that need to be converted into national applications within a period of maximum 30 months in order to obtain a patent. Each country in which a national application is lodged has its own process and criteria for patentability.

2. **Patent applications are NOT the same as granted patents.**

   A patent application undergoes an examination process to see if it meets the patentability requirements of the country it is lodged in. During this process, the claims are often amended. Thus, a patent application contains claims reciting what an applicant hopes to get protection for, but the claims in the granted patent may be different, an d only an issued patent contains claims that have legal protection.

# PATENTS TOP 10

3. **Patents are examined, they are NOT peer-reviewed.**

   Patent examiners assess an invention against the relevant prior art publicly available in the field of the invention to determine whether it fulfills the patentability criteria. The requirements for patentability are not the same as the criteria used for publishing research results in a scientific journal. They may appear to be more lenient, or much more stricter. The most important criteria for patenting generally are whether the invention is enabled by the description submitted, and whether it appears to have been described or obvious from what was already in the public domain before filling. The subject for a publication may be quite impactful without fulfilling the patentability criteria.

# PATENTS TOP 10

4. **The applicant or assignee of a patent may not be the actual holder of the patent rights.**

   Patents are commercially tradable assets and the rights can be assigned or licensed to third parties.

5. **Patents have a limited lifetime.**

   In most countries now, a patent last for 20 years from the date of filing provided required maintenance fees are paid. This period is the monopoly period granted to the owner of the patent.

6. **Patent are rights with geographic boundaries.**

   Patents are granted by the government of a country or jurisdiction and the rights are valid only within its territorial boundaries.

# PATENTS TOP 10

7. **Infringement of a patent is generally a legal matter between parties.**

   In most countries, infringement is a civil wrong where a person's right are violated and is upto to the offended party to sue for damages or seek  other legal remedies. In some countries, including some European countries, infringement of a patent is an act committed against the sate and may be punishable by fines and imprisonment.

8. **Claims define the limits of a patented invention and the boundaries of the patent rights.**

   not the titles, not the abstract, not the detailed description of the invention, not the examples and figures.

# PATENTS TOP 10

9. **A patent does not guarantee that anyone will license the invention.**

   As is the case for any tradable asset, a patent needs to be promoted, offered in the market and commercialized actively in order to generate income for its owners. May patents do not generate any income, and if this is the case, sometimes owners choose to allow them to lapse early.

10. **Patent rights are exclusionary rights.**

    Patent rights can be used to stop other parties from using, making, selling, offering to sell, and importing the protected invention if the other parties doe not have authorization from the holder of the patent rights.

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